Osteosynt

CE 1023

HA/TCP Micro-macro porous biphasic calcium phosphate Bioceramic

DESCRIPTION

OSTEOSYNT® C.M.O. is a matrix of a morphogenetic complex as a bioactive and biomimetic last generation of biphasic calcium phosphate bioceramic, 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 has two phases: an amorphous (i.e. more soluble, corresponding to β-TCP) and a crystalline (i.e. more stable, corresponding to HA), usually in the range of 60% HA/ 40% β-TCP, with possible variations. These components and features (chemical composition and physical structure) mimic bone mineral matrix and dental enamel and guarantee the intrinsic osteoinduction (chemotaxis) and osteoconduction (haptotaxis) properties to this bioceramics, which are crucial steps for the bone regeneration process.

OSTEOSYNT® C.M.O. is characterized by forming a bone morphogenetic complex (Patent Letter nº PI9104220-8).

OSTEOSYNT® C.M.O. is biocompatible and presents necessary mechanical resistance, which is clearly noticed under normal compression during application to the surgical bed. It is gradually resorbed, providing the required support for new bone formation, 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, systemic reactions and other biological risks. Radiologically, it is radiopaque, due to its calcium (Ca) content, which facilitates its identification.

OSTEOSYNT® C.M.O. has micropores, with diameters ranging from 1 to 10µm. Consequently, this bioceramics has significant capillarity and surface tension, which favors the storage, the transport and release of patient's own proteins - as individual signaling morphogenetic factors - or extrinsic substances, such as growth factors, antibiotics, and drugs for chemotherapy. These characteristics favor the intrinsic osteoinduction property of this material. The physical geometry of the pores represents an additional advantage of this bioceramics compared to others that lack these features, since osteogenesis (bone neoformation) is geometrically dependent.

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

FORMS OF THE PRODUCT

OSTEOSYNT® C.M.O. is available in different forms:

- Granules
- Applicator with granules
- Blocks
- Wedges
- Intersomatic devices (cages)
- Buttons
- Spheres
- Custom-made devices (individualized pieces or individual parts – obtained through prototyping, using CT scan images, according to DICON protocol).

All of them present interconnected micro-, meso- and macropores, and nanostructured surface.

Granules are also available with applicator, containing 0.5 g to 10.0 g (0.40 cm^3 to 8.00 cm^3). The product is indicated for cavitary or segmental bone defects, as inlay or onlay grafts, and must be in contact with remaining viable bone tissue.

Chemical safety of Osteosynt is based on the recognized consensus standard specification, ASTM F 1185-88 (reapproved 1993) Composition of Ceramic Hydroxyapatite for Surgical Implants. Osteosynt conforms to the required specifications for heavy metals trace elements level. The biocompatibility of HA, β-TCP, mixture of both and Osteosynt is well documented. All these biomaterials have consistently proven to be non-toxic, non-allergenic, biocompatible and elicits no inflammation. No adverse effect or foreign body reaction have been reported.

MEDICAL DEVICE CLAIMS

OSTEOSYNT® C.M.O. is a synthetic bioceramics for bone reconstruction/regeneration that has several advantages and benefits when compared to autologous bone grafts, biologically derived biomaterials, and other classes of synthetic biomaterials, such as polymers. Therefore:

OSTEOSYNT® C.M.O. does not require another surgical procedure to be harvested, as is the case for autologous bone grafts. Consequently, the use of OSTEOSYNT® C.M.O. decreases the time and the costs of surgeries, as well as the pain, blood loss and discomfort of the patient at the postoperative period.

OSTEOSYNT® C.M.O. does not present risks of disease transmission and of several other pathogens, as known with grafts of animal (biological) origin.

OSTEOSYNT® C.M.O. mimics the composition of bone tissue and does not elicit foreign body reaction or exacerbated inflammation.

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

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

OSTEOSYNT® C.M.O. is stable over time and will not present distortions nor cause aesthetics or functional shortcomes;

OSTEOSYNT® C.M.O. is easily handled and applied.

OSTEOSYNT® C.M.O. is available in different presentation forms, giving the surgeon more options for his/her surgical planning.

OSTEOSYNT® C.M.O. is fabricated by a well-controlled process, which allows obtaining a biomaterial with fully reproducible chemical composition and physical features.

Other Claims: OSTEOSYNT® C.M.O. can be mixed with patient's own blood and/other cell types before application, as well as other molecules such as drugs, fibrin and L-PRF, without losing its chemical and physical features and properties.

OPERATION PRINCIPLE

OSTEOSYNT® C.M.O. is a bioactive and biomimetic biphasic calcium phosphate bioceramics, that presents interconnected pores of different sizes, nanostructured surface (surface topography) and is available in several presentation forms. It comprehends a desirable scaffold that will remain stable and active for the time required for the deposition and maintenance of newly formed bone tissue, which adheres to its surface by chemical process

(mineralization of amorphous cementing substance) and due to the physical features of its surface (nanostructured surface). Newly formed bone and blood vessels penetrates the biomaterial's pores, fully incorporating it into the new tissue, and turning it into an integral part of the bone. The bioceramics also provides support for the deposition and accumulation of substances and patient's own proteins, which will favor tissue neoformation. It also induces osteoblastic differentiation of cells, a process that is related to the controlled release of calcium and phosphate ions into the surgical site, that naturally occurs during the dissolution and/or resorption process of the bioceramics. These ions, however, do not induce abnormal calcium or phosphate levels in urine, serum, or organs such as liver, skin, heart, kidney, lung and intestine. Therefore, bioceramics function as a conductor and intrinsic inductor of the process, without losing its mechanical resistance.

Its replacement occurs gradually by the process of bone remodeling, which relies particularly on osteoclastic activity, that is observed within the microenvironment after the maturation of the newly formed bone. The length of time that OSTEOSYNT® C.M.O. remains in the body varies according to the organic capacity for bone formation and remodeling, and the presentation form of the biomaterial.

WARNING

OSTEOSYNT® C.M.O. must be applied after the surgical site is completely cleaned, i.e. after removal of fibrosis, debris and dead or infected tissues.

OSTEOSYNT® C.M.O. must be packed and accommodated into the surgical site, as is usually performed with autografts, and be in contact with viable and bleeding bone tissue (even if only one bony wall is present).

Ensure adequate covering of OSTEOSYNT®, regardless of its form of presentation, with healthy

soft tissue, which must be sutured without tension.

NOTE: OSTEOSYNT® C.M.O. can be mixed with 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, without losing its chemical and physical features and properties.

INTENDED USE

OSTEOSYNT® C.M.O. is an elective bioceramics indicated for 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
- Craniofacial Surgery
- Ophthalmology
- Otorhinolaryngology
- Spinal Surgeries

INDICATIONS

OSTEOSYNT® C.M.O. is indicated to treat fractures; segmental and cavitary bone losses, sinking; dehiscence; pseudoarthrosis; bone infectious processes that have been treated; sequelae of osteomyelitis; osteolysis; treatment of cysts and tumors; placement and revision of hip and knee prosthesis; arthroplasties; laminectomies; arthrodesis including in spinal fusions; osteotomies; aesthetic repairs and bone augmentations (as inlay or onlay grafts); reconstruction of long, short, flat bones of the locomotor system and skull, face and mandible, including septorhinoplasties (replacement of septal skeleton, in cases where it is absent or nonusable, in Otorhinolaryngology); to maintain the volume of structures as required in cases of removal of the eyeball or its contents (application in Ophthalmology); flap reconstructions; to fill dental alveolar bone; alveolar ridge reconstruction; implantology and cosmetic reconstruction; sinus lifting; craniotomies; craniectomies; correction of congenital deformities; ostectomies; for placement of dental implants; for the stabilization of osteotomies and prosthesis in general, both in medicine and dentistry, and for facial reconstructions.

OSTEOSYNT® C.M.O. is available in different forms (Table 1):

Granules: Granules are indicated to treat fractures, in segmental and cavitary bone losses, to treat pseudoarthrosis, in treated infectious processes, sequelae of osteomyelitis, osteolysis, revision of hip and knee prosthesis, arthroplasties, to treat sinking, dehiscence, to treat cysts and tumors, in laminectomies, spinal fusions, osteotomies, bone augmentation (as inlay or onlay grafts), in Orthopedics and Traumatology, Spinal surgeries, Neurosurgery, Oral and Maxillofacial Surgery, Dentistry, Reconstructive Plastic Surgery and Craniofacial surgery.

Blocks: Blocks are indicated to stabilize osteotomies and to maintain spaces, including in high-load areas, in Orthopedics and Traumatology, Oral and Maxillofacial Surgery, Dentistry, Reconstructive Plastic Surgery and Craniofacial surgery.

Applicator with granules: Applicator with granules is indicated to fill bone cavitites and as onlay grafts in Orthopedics and Traumatology, Oral and Maxillofacial Surgery, Dentistry, Reconstructive Plastic Surgery and Craniofacial Surgery.

Wedges: Wedges are indicated to stabilize osteotomies in Orthopedics and Traumatology, Reconstructive Plastic Surgery, Craniofacial Reconstructions and Oral and Maxillofacial Surgeries.

Intersomatic devices (cages): Intersomatic devices (cages) are indicated for spinal fusions, in Spine Surgeries.

Buttons: Buttons are indicated in cranioplasties, after ostectomies or osteotomies, in Neurosurgery and Craniofacial Surgery.

Spheres: Spheres are indicated to replace the eyeball or its content, in Ophthalmology.

Custom-made devices (individualized pieces or individual parts): Individualized pieces are indicated for skull and facial reconstructions, including the reconstruction of nasal septum, as well as for long and short bones, in Craniofacial Reconstructions, Oral and Maxillofacial Surgeries, Dentistry, Neurosurgeries, Reconstructive Plastic Surgery, Otorhinolaryngology and Orthopedics and Traumatology.

Table 1: Presentation forms that are indicated for each area of expertise.

Areas of Expertise	Presentation Forms
Orthopaedics and Traumatology	Granules , Wedges, Blocks , applicator with granules , Individualized pieces.
Spinal Surgery	Granules, Cages .
Neurosurgery	Granules, buttons, Individualized pieces.
Reconstructive Plastic Surgery	Granules , Wedges, Blocks , applicator with granules , Individualized pieces.
Craniofacial Surgery	Granules , Wedges, Blocks , applicator with granules , Individualized pieces.
Oral and Maxillofacial Surgery	Granules , Wedges, Blocks , applicator with granules , Individualized pieces.
Dentistry	Granules, Blocks , applicator with Granules.
Otorhinolaryngology	Individualized pieces.
Ophthalmology	Spheres

NOTICE

OSTEOSYNT® C.M.O., in all its presentation forms, is indicated for bone reconstruction.

OSTEOSYNT® C.M.O. is indicated for pediatric and adult patients (1.5 to 90 years-old).

OSTEOSYNT® C.M.O. does not induce immunological or cytotoxic reactions.

CONTRAINDICATIONS WARNING

The use of OSTEOSYNT® C.M.O. in the presence of infection and/or necrotic and/or

compromised tissues, without treatment, is not indicated.

Its use in patients with systemic diseases, such as diabetes mellitus, AIDS, osteoporosis, diseases, or situations that lead to bone demineralization, or who are on corticotherapy 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 predictable.

Contraindication also include 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 cartilage)

and epiphysis. Therefore, these applications must 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, osseous ingrowth into bone void, as is possible with any bone void filler.

Can result from using the bioceramics in patients that are prone to allergic reactions to products derived from calcium salts.

Complications related to wound healing, such as bruising, swelling and infection may occur, as in any other surgical procedure.

TARGET POPULATION

OSTEOSYNT® C.M.O. is indicated for pediatric and adult patients (1.5 to 90 years-old) 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 maxilla reconstructions, sinus lift and alveolar bone reconstruction and/or augmentation.

PREGNANCY / BREASTFEEDING

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

WARNING: For safety reasons, pregnant or nursing women shall not be treated with the OSTEOSYNT® C.M.O. product.

WARNINGS AND PRECAUTIONS

Rigid fixation techniques may be required to assure 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, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes (but is not limited to) individuals with long-term steroidal therapy or treatment acting on the calcium or phosphorus metabolism.

Osteosynt is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

Osteosynt 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:

Existence of a scaffold that allows vascular neoformation, cell migration, adhesion and proliferation, and deposition of bioactive molecules.

Existence of patient’s own bioactive molecules, such as BMPs (bone morphogenetic proteins), naturally occurring in the body.

Existence of specific cells (such as stem cells and osteoprogenitor cells), naturally existing in the body.

Vascularization, adequate blood supply.

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

Complications associated with the use of OSTEOSYNT® C.M.O. recorded so far are mainly related to surgical techniques and procedures, and comprehends particle extrusion, granule migration, soft tissue dehiscence and delayed healing. However, these complications may not necessarily compromise final clinical results; therefore, it is mandatory to perform the adequate preparation of the surgical site and the use of proper surgical technique, to allow the conditions mentioned above to exist.

NOTICE

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

Removal of fibrosis and devitalized tissue from the surgical site, before implantation of the bioceramics;

Proper cleaning of the surgical site;

Use sterile surgical instruments;

The use of aseptic technique to prepare and to apply the product;

To ensure direct contact of the product with a clean, healthy and bleeding remaining bony tissue, even if the bioceramics presented in applicator with granules is used;

WARNING

The surgical use of OSTEOSYNT® C.M.O. must be restricted to qualified and trained professionals, since the improper application can result in relative failure and/or migration of the product;

Proper preoperative evaluation, correct indication of the presentation form and use of adequate surgical techniques, proper handling of the biomaterial as indicated, as well as postoperative monitoring and control, are necessary for the desirable results to be achieved;

Patients must be properly advised regarding the postoperative care.

Professional and patients must be advised that this material is radiopaque, visible under X- rays 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 must be avoided.

Inform patients: Physical activities may be restricted during the recovery period and must be assessed according to the type of surgery, extent of the lesion and place of application. The time limits for walking and/or moving may vary, always obeying the professionals' recommendations.

The desirable period of time required for tissue neoformation is usually similar to that where autografts are used, 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 informing the name and type of the product, batch and series numbers, date of manufacture and expiration date of the product are provided and must be attached to the medical records, health insurance documents, hospital files, tax documents and patient documents, as determined by national and international standards and rules.

Additionally, labels to be filled with data related to the patient that received the implant of bioceramics, the surgical procedures and the presentation form of the biomaterial is provided and must be filled out by the professional/team that open and apply the biomaterial. This guarantee the traceability of the bioceramics, which is responsibility of the professional who attends the patient.

TRACEABILITY

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

NOTICE: We recommend that the surgeon responsible for the implantation of the biomaterial, inform the distributor and/or another agent of the chain about the implanted product, patient and type of surgery. Labels for the collection of such information, i.e. patient's name, implantation date, customer's CNPJ or patient's CPF (identification numbers), are provided within the packaging of OSTEOSYNT®.

STERILIZATION

The products are sterilized with ethylene oxide.

The sterilization process ensures a Sterility Assurance Level (SAL) of 10^{-6}.

WARNING; The product is sterilized in ethylene oxide (ETO), for single use. Do not reuse. Do not re-sterilize the product.

Do not use if the package is broken;

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

PROCEDURES

Upon receipt of the Product:

Check the description, according to the purchase request (type of material, shape of the piece etc).

Check the manufacturing lot and expiration date on the labels and/or packaging box (cartridge).

Remove the product from the surgical grade envelope, only inside the operating room, using aseptic technique, and when performing the surgical procedure.

ATTENTION: For products available in a glass vial, carefully remove the aluminum seal.

PREPARATION AND USE OF THE PRODUCT IN GRANULES

Prepare the product: Prepare the product on site, according to aseptic techniques. The product can be used pure, i.e. 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 be associated with blood and/or autogenous medullary bone, blood derivatives, fibrin, platelet concentrate and/or cellular concentrates, obtained from the patient, always observing its ability to lead to desirable results, regardless of the association with any exogenous substances or molecules, such as bone morphogenetic proteins (BMP´s) and/or concentrates of specific cells, including platelets. This is so because of the bioceramics' capacity to absorb and adsorb fluids and molecules and to favor cell deposition. The product can be mixed with punctured medullary blood carrying stem cells. Each gram of OSTEOSYNT® C.M.O. in granule form has the capacity to absorb approximately 0.7 cm3 to 0.8 cm3 of medullary blood.

NOTE: Each gram of OSTEOSYNT® C.M.O. in the form of granules has the possibility 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.

Due to the indication, it can also be associated with binders, such as organic or synthetic polymeric materials that allow its modeling for the desired function and results, depending upon the situation and indication of use.

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

The physicochemical characteristics and properties indicate the use of OSTEOSYNT® C.M.O. as a vehicle for release of drugs such as antibiotics, proteins, chemotherapy and others.

It is essential to fully fill the surgical space corresponding to the bone loss using proper compaction of the bioceramics. This provides the reconstructed area with adequate resistance to compression, containment of the biomaterial to the surgical site and stabilization of the area.

OSTEOSYNT® C.M.O. with applicator must be applied directly to the surgical site, without being mixed with patient's blood before use. It does not need to be pre-molded, as it easily adapts to the defect.

FASTER EVOLUTION/REGENERATION AND BETTER RESULTS

To make an efficient cleaning of the surgical site so that the product has direct contact with healthy bleeding bone, allowing immediate blood absorption.

To mix the product with patient's own venous or medullary blood. Each gram of granulated OSTEOSYNT® C.M.O. has the capacity to absorb approximately 0.7 cm^3 of blood.

The mixture of the product with other morphogenetic substances, drugs, cells and/or tissues can influence the process of tissue neoformation.

USING BLOCKS AND CUSTOM-MADE DEVICES

OSTEOSYNT® C.M.O. in the form of blocks and/or custom-made devices can be perforated and modeled with the use of a drill, the lateral surface of which must be gently passed over the biomaterial.

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

DISPOSAL / ELIMINATION

The violated, expired or remaining product that is not used in surgeries must have the environmentally correct destination, according to the current legislation.

PACKAGING

The product is individually packed in a surgical grade envelope, which in turn, is sterilized and placed in a cardboard cartridge.

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

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

COMMENTS

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

Products with other dimensions can be supplied, upon request.

ADVERSE REACTION NOTIFICATION

In case of suspicion of any unreported event or even product change, EINCO Biomaterial Ltda. must be communicated immediately, by calling 00 55 (31) 3335-2905, through the website (www.eincobio.com.br) or e-mail (eincobio@eincobio.com.br).

	Dimension	Quantity	Code
Granules - Dentistry	10-20 mesh (200-850) micra	0,5 g 1 g	OSGD 0,5 [10:20] OSGD 1 [10:20]
	20 – 40 mesh (850 – 425) micra	0,5 g 1 g	OSGD 0,5 [20:40] OSGD 1 [20:40]
	40 – 60 mesh (425 – 250) micra	0,5 g 1 g	OSGD 0,5 [40:60] OSGD 1 [40:60]
	60 – 80 mesh (250 – 180) micra	0,5 g 1 g	OSGD 0,5 [60:80] OSGD 1 [60:80]
	100 – 200 mesh (150 – 75) micra	0,5 g 1 g	OSGD 0,5 [100:200] OSGD 1 [100:200]
Granules - General	05 – 10 mesh (4000 – 2000) micra	2 g 5 g 10 g	OSGP 2 [5:10] OSGP 5 [5:10] OSGP 10 [5:10]
	10 – 20 mesh (2000 – 850) micra	2 g 5 g 10 g	OSGP 2 [10:20] OSGP 5 [10:20] OSGP 10 [10:20]
	20 – 40 mesh (850 – 425) mesh	2 g 5 g 10 g	OSGP 2 [20:40] OSGP 5 [20:40] OSGP 10 [20:40]
	40 – 60 mesh (425 – 250) micra	2 g 5 g 10 g	OSGP 2 [40:60] OSGP 5 [40:60] OSGP 10 [40:60]
	60 – 80 mesh (250 – 180) micra	2 g 5 g 10 g	OSGP 2 [60:80] OSGP 5 [60:80] OSGP 10 [60:80]
	100 – 200 mesh (150 – 75) micra	2 g 5 g 10 g	OSGP 2 [100:200] OSGP 5 [100:200] OSGP 10 [100:200]
	200 – 400 mesh (75 – 28) micra	2 g 5 g 10 g	OSGP 2 [200:400] OSGP 5 [200:400] OSGP 10 [200:400]]
Applicator with Granules	100 – 200 mesh (150 – 75) micra	0,5 g 1 g 2 g 5 g 10 g	OSGI 0,5 [100:200] OSGI 1 [100:200] OSGI 2 [100:200] OSGI 5 [100:200] OSGI 10 [100:200]
Spheres	Sphere 14 mm	01 unid	OSEP Ø 14 mm
	Sphere 16 mm		OSEP Ø 16 mm
	Sphere 18 mm		OSEP Ø 18 mm
	Sphere 20 mm		OSEP Ø 20 mm
Blocks	Segment 5x5x5 mm	01 unid	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 t 8x15x25 mm		OSBP 8.15.25
	Segment 10x10x10 mm		OSBP 10.10.10
	Segment t 10x10x40 mm		OSBP 10.10.40
	Segment 6x15x50 mm		OSBP 6.15.50
Wedges	Segment 6x8x10x12 mm	01 unid	OBBC 6.8.10.12
	Segment 6x8x12x20 mm		OSBC 6.8.12.20
	Segment 8x10x15x25 mm		OSBC 8.10.15.25
	Segment 3x5x15x10 mm		OSBC 3.5.10.15.25
	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
Intersomatic Devices (Cages)	Segment 6x4x10x12 mm (T1)	01 unid	OSTC 6.4.10.12
	Segment 6x4x12x12 mm (T2)		OSTC 6.4.12.12
	Segment 6x4x14x12 mm (T3)		OSTC 6.4.14.12
	Segment 8x6x10x12 mm (T4)		OSTC 8.6.10.12
	Segment 8x6x14x12 mm (T5)		OSTC 8.6.14.12
	Segment 10x8x10x12 mm (T6)		OSTC 10.8.10.12
	Segment 10x8x12x12 mm (T7)		OSTC 10.8.12.12
	Segment 10x8x14x12 mm (T8)		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 unid	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
	Device/Stem special (individualized pieces, individual parts) Custom Made Device		

MADE BY

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EC REP

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