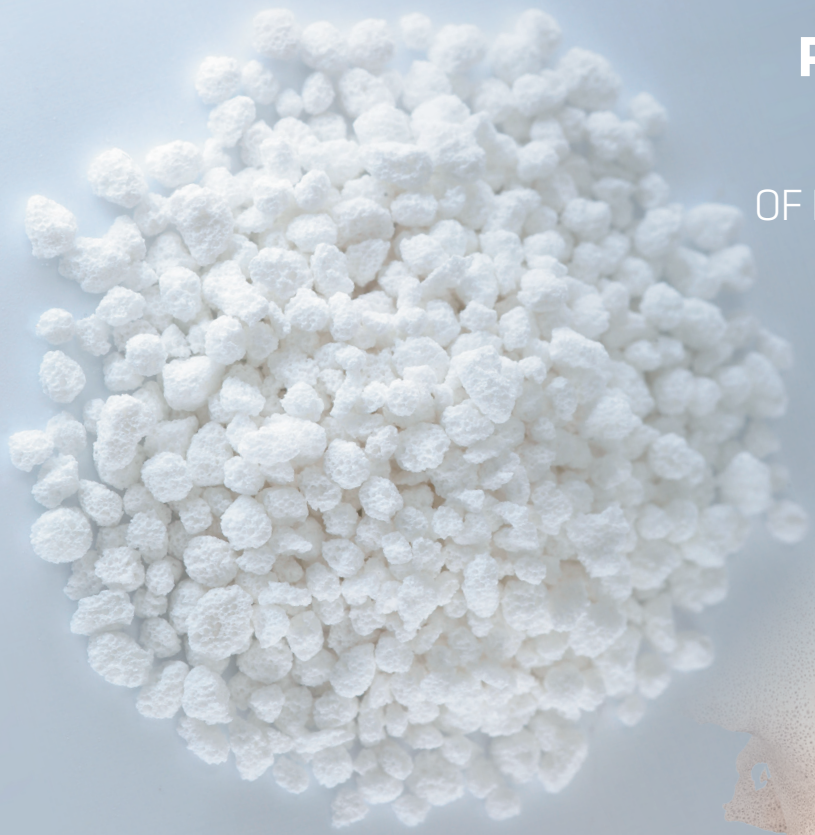
RIGENERA
MANUAL

btk Implanting Trust, Smile Again!

RIGENERA

RIGENERA^{BCP} GRANULES AND RIGENERA 3D

INNOVATIVE FORMULATION
OF BIPHASIC CALCIUM PHOSPHATE



GRANULES
0.25-1.0 mm
1.0-2.0 mm

3D
CUSTOM

visit **btk.dental**

IMPORTANT NOTE

For latest updates and information, **visit www.btk.dental**

This manual provides dental practitioners and related specialists with general information regarding the use of the formulation of biphasic calcium phosphate in granules and in customized blocks for regenerative and reconstructive bone surgery RIGENERA.

For detailed information on other specific implant lines and their restorative procedures, please refer to the corresponding manuals, specific literature or refer to the BTK website.

Consider to regularly visit practical courses for updates and professional exchange with dedicated colleagues in order to ensure your long-term success with implant-borne dental restorations.

btk Implanting Trust, Smile Again!

RIGENERA

Formulation of biphasic calcium phosphate in granules and in customized blocks for regenerative and reconstructive bone surgery

INDEX

CORPORATE BACKGROUND

Privately held BTK BIOTEC was founded in 1998 in order to improve the quality of life of people with missing teeth.

BTK is a dedicated supporter of the genuine "100% Made in Italy" label, because with this it is guaranteed that BTK products are of unmatcheable Italian craftsmanship and premium quality materials offering dedicated specialization and ample differentiation.

BTK HEADQUARTERS - NORTH ITALY

Implanting Trust, Smile again!

By combining cutting-edge technologies and biology, BTK's mission is to offer affordable and personalized implant-borne solutions thereby sustainably improving the daily life of dental patients.

Together with leading professionals, BTK strives to become a reference in replacing missing teeth with trusted implant solutions in order to improve oral health around the globe.

IMPLANT PORTFOLIO

BTK is dedicated to offer comprehensive implant solutions to meet the requirements of individual clinical situations, user preferences and economic constraints.

Different designs, sizes, diameters, surfaces and abutment connections are available, while at the same time BTK strives to maintain a small number of precision-instruments thus simplifying procedures and limiting investments needed.

Based on the implant family, BTK provides specific surgical kits. The surgical kits are used to safely store and sterilize the surgical and auxiliary instruments of BTK implant systems.

PROSTHESIS SOLUTIONS

It has never been easier to obtain functionality and an immediate aesthetic result, thanks to the various temporary and definitive abutments, which can be used on all our implant lines!

For situations where the immediate loading protocol is not indicated, all dedicated prosthetic components are also available, such as healing abutments and cover screws.

In addition, we offer solutions for traditional and digital impression taking and for various prosthetic techniques.

CUSTOM-MADE MEDICAL DEVICES

We are a leading company in the field of digital dentistry and, thanks to the potential of new technologies, we offer a range of unique products, to assist the clinician in solving the most complex cases presented to him in the dental practise.

In this sense, we propose solutions such as IUXTA-3D, 3D-MESH and RIGENERA 3D that serve to solve those situations of large atrophies of the upper and lower jaws, which do not allow the use of classic dental implants.

All these solutions are 100% customized on the anatomy of each individual patient, in this way we guarantee the highest quality, precision and adaptation to every situation.

MADE IN ITALY, USED GLOBALLY

We constantly ensure that the quality of our products and services meet the high expectations of our customers and their patients. Specialized professionals are taking care to offer comprehensive solutions in applied research, engineering, education and related activities.

Our brand is a solid promise of quality, we are certified UNI EN ISO 9001, UNI EN ISO 13485 and MDD 93/42/EEC and subsequent amendements and additions, and is therefore authorized to apply the CE Mark on its products.

The Biotec Company is registered at Italian Health Ministry Register of custom-made medical device manufacturers.

REABSORBABLE BONE REGENERATOR

RIGENERA

RIGENERA is an innovative, safe, and reliable bone substitute.
It is totally synthetic and characterized by controlled resorption properties and extraordinary manipulation features.

The bone substitutes are used in many dentistry fields to solve complex clinical situations like:

- GBR techniques, sinus lift and socket preservation
- GTR techniques, under bone pockets
- endodontic surgery
- oral surgery.

Rigenera is a synthetic, porous biomaterial designed for the treatment of bone defects and suitable for any clinical situation.

The PERFECT MIX of hydroxyapatite (HA) and β-Tricalcium phosphate (β-TCP), guarantees a perfect balance between resorption and graft stability.

BTK RIGENERA is composed by **30% of low absorbed hydroxyapatite (HA) and 70% of rapid absorbed β-Tricalcium phosphate** (β-TCP). The exclusive production process based on the synthesis guarantees a totally uniform distribution of both mineral phases.

The composition of RIGENERA encourages the fast creation of newly formed vital bone by ensuring a long-term volume stability.

FEATURES

- **OSTEOCONDUCTIVE**
- **ULTRA-HIGH INTERCONNECTED POROSITY**
- **FAST CREATION AND SUBSTITUTION OF BIOMATERIAL WITH VITAL BONE**
- **GRAFT VOLUME AND STABILITY BECAUSE OF EXCELLENT FITTING**
- **SAFE, RELIABLE AND STERILE**
- **HIGHLY HYDROPHILIC SURFACE**
- **100% SYNTHETIC AND ABSORBABLE**

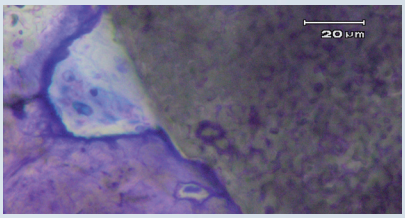
IDEAL OSTEOCONDUCTIVE PROPERTIES

The osteoconductivity of RIGENERA is based on a matrix of interconnected pores with a total porosity of 70%.
Thanks to a widespread micro-porosity, the nanostructured surface eases the absorption of blood, proteins, and growth factors and it promotes the cells differentiation and bone integration.

RIGENERA is the perfect scaffold for the migration of osteoprogenitor cells and signalling molecules, which can speed up the tissue integration and regeneration.

BENEFITS

- It preserves the shape and the volume of the defect and avoids the bone resorption.
- It eases the fast cells colonization.
- It works as ideal support as it is recognized by human body. (see Picture 1)



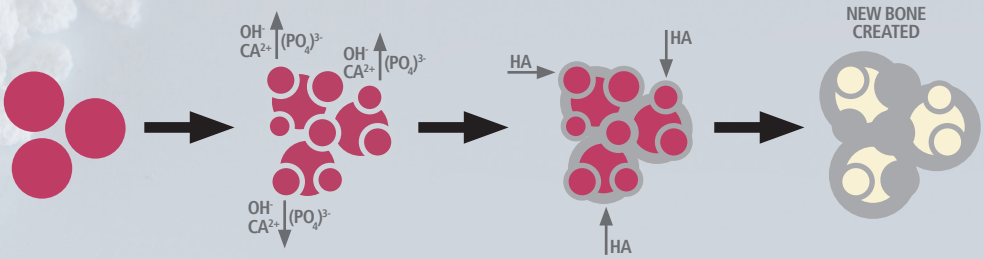
Picture 1- Vessels and cells adhering to RIGENERA to create new bone.

PROPERTIES

After being placed into the to-be-regenerated area, RIGENERA is subjected to a quick dissolution thanks to its β-TCP component, and it releases Ca^{2+} and PO_4^{3} ions.

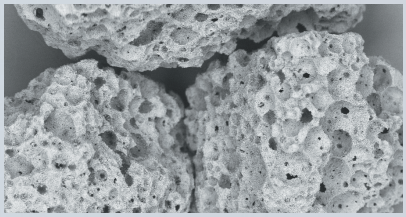
These work as molecular signal that leads to the precipitation of hydroxyapatite on the grafting surface, which produces an interphase (of few micron thick) where there are collagen, osteoblast, and fibrous bone tissue.

They appear first as amorphous substance and then they develop themselves by becoming structured; the graft dissolution follows from the inside by reaching the substitution with new bone as result. (see Picture 2)



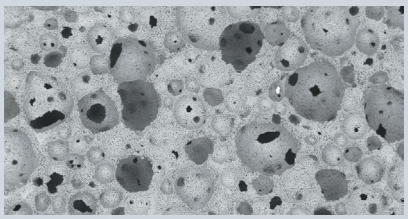
Picture 2 - The whole resorption process of RIGENERA (physiological behaviour of β-TCP).

The most important feature of RIGENERA is its three-dimensional structure (see Picture 3), **with a porosity average value of 70% and an average pores size of 250 micron.**
This interconnected porosity eases the cellular and vascular colonization process.

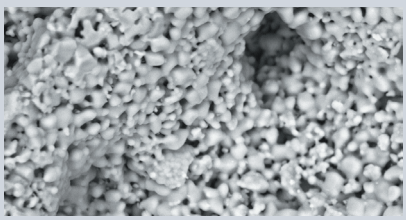


Picture 3 - Three-dimensional structure of RIGENERA.

RIGENERA macro-porosity and micro-porosity (see Picture 4 and 5) ease the colonization of biomaterial by the bone, the generation of osteoblast and new bone on the whole biomaterial (and not only on its surface like other biomaterials).

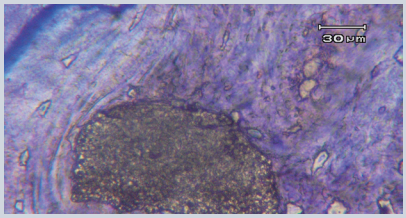


Picture 4 - Macro-porosity of RIGENERA.



Picture 5 - Micro-porosity of RIGENERA.

The interconnected mesh structure involves the cells penetration into the graft; while the micro-porosity guarantees the integration of vessels even in the most inner part, by including all the growth factors required for the new bone generation. This increases the osteoconductivity of the graft (see Picture 6).



Picture 6 - Increase of graft osteoconductivity.

These features lead to a reduction of bone regeneration time if compared to other regenerators.

RIGENERA BIPHASIC PROCESS

An ideal bone regeneration material should be reabsorbed during the creation of a new bone matrix. RIGENERA involves osteoblast and osteoclast, and it is characterized by an initial integration of the material into the surrounding bone matrix and by a gradual degradation.

RIGENERA is a homogeneous biphasic biomaterial containing 30% of HA and 70% of β-TCP.

The most used calcium phosphates are the hydroxyapatite (HA), the α-Tricalcium phosphate (α-TCP) and the β-Tricalcium phosphate (β-TCP).

The HA has a slower solubility and so it provides the maximum stability; indeed, the β-TCP shows a higher solubility and a faster resorption reaction.

The basic principle of RIGENERA, and more in general of the biphasic calcium phosphates, is to reach a balance between the hydroxyapatite (HA) properties, which can be detected several years after the implant, and the α-Tricalcium phosphate (β-TCP), which is characterized by a quite rapid resorption.

The materials for the bone regeneration based on blends of HA and β-TCP have been used in the restorative dentistry surgery for more than 20 years.

INDICATIONS FOR USE

- Filling material for maxillary and mandibular cavities after teeth extraction by avoiding the resorption of the alveolar process.
- Filling material for oral surgery of cavities dued to impacted teeth extraction.
- Filling material for bone fenestrations where the buccal-lingual ridge size is reduced.
- Filling material of bone cavities after the loss of a tooth when implant replacement is impossible.
- Maxillary sinus lifting.
- Horizontal and vertical ridge restorations through GBR techniques.
- Periodontal intraosseous defects.
- Bifurcation injuries.

WARNINGS

Avoid the use of RIGENERA in case of chronic or severe infections not properly treated with antibiotic.
Do not use in areas without a primary stability of the implant or in those areas which exclude the possibility of bone growth around the implant.

To avoid the waste of material if used in great quantities, please consider the possibility of using a membrane to cover the graft.
To increase the adhesion of the biomaterial, it is recommended to wet it with saline solution or patient's blood.

CLINICAL BENEFITS
RIGENERA

INCREASE OF OSTEOCONDUCTIVITY

Regarding the osteoconductivity (to support the vessels which will vascularize again the defect area and for the osteogenic cells of the recipient site) RIGENERA works exactly as autografts or allografts of spongy bone, thanks to its open and interconnected porous structure.

EXCELLENT PRESERVATION OF THE VOLUME AND THE PRIMARY STABILITY OF THE GRAFT

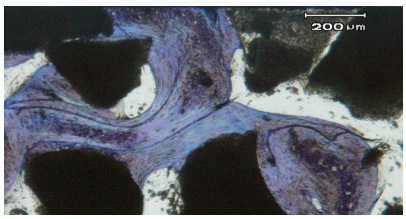
RIGENERA protects the adjacent bone against the resorption.
Thanks to it porous structure, the anchoring effect of RIGENERA allows the preservation of the shape and the volume stability of the grafted area.
This results into an excellent fitting by avoiding unwanted micro movements of the graft.

TOTAL ABSENCE OF IMMUNOLOGICAL ACTIVITY

RIGENERA is completely synthetic and immunologically inactive and free of antigenic elements.

EFFECTIVE BONE REGENERATION

There is evidence that the filling of bone defect with RIGENERA remarkably increases the scarring process of the defect.
Several studies have shown that besides speeding up the stabilization process, RIGENERA is perfectly osteointegrated in the bone tissue with a total osteocompatibility and it contributes to the bone reshaping process of the defect by restoring the osteons.



Osteonal remodeling

NO INFECTIONS

RIGENERA has been developed in strictly aseptic conditions and is delivered in a sterile state so there is no risk of infections due to the nature of the material.

NO AUTOLOGOUS BONE IS NEEDED

RIGENERA is made to be used without the support of the patient's bone.

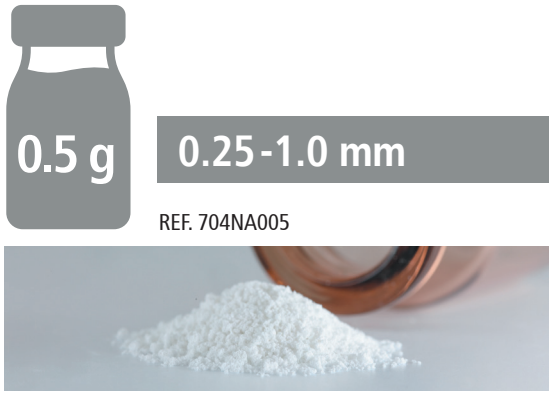
RADIOPACITY

RIGENERA is radiopaque and it allows to monitor the bone integration and resorption.

RIGENERA^{BCP}
GRANULES

The spongy bone structure and the porosity of RIGENERA^{BCP} granules allow a rapid absorption of blood and a quick supply of the surgery site with vital cells.

Instructions in case of guided bone regeneration:
- RIGENERA^{BCP} granules must be covered with a barrier membrane for the GBR
- As an alternative to the use of membranes, it is recommended to use customised 3D-MESH titanium grids
- This avoids the resorption and the inside growth of soft tissues into the bone graft

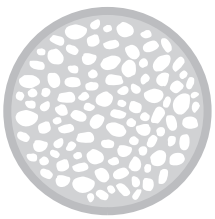


REF. 704NA005

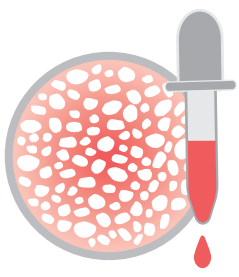
REF. 704NA020

INDICATIONS FOR USE

RIGENERA^{BCP} morphology allows the granules to be hydrophilic and increases the absorption and agglomeration of fluids by easing the application to the site and the surgery. The result is an ease of use and handling for every clinical situation.

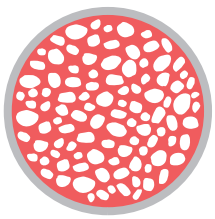


1. Pour the granules of RIGENERA^{BCP} into a sterile basin.



2. Hydrate the granules with saline solution or patient's blood.

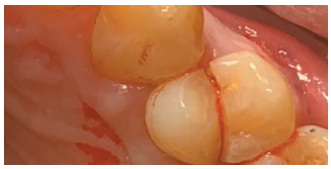
3. Combine the granules with the liquid. The combination and preparation of RIGENERA^{BCP} with every kind of substance are under the doctor's responsibility.



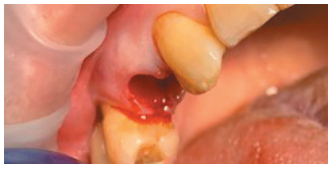
4. The biomaterial is ready to be applied.

CASE 1: **HANDLING OF AN ALVEOLAR POCKET AFTER EXTRACTION**
GRANULES 0.5g - 0.25-1.0 mm

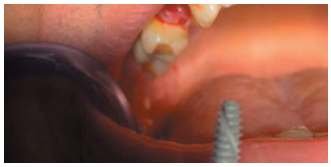
Male Patient, 71 years old, non-smoker.



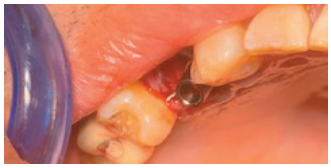
1. Fracture of tooth 1.4.



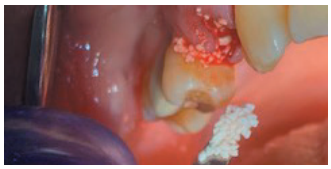
2. Extraction of the damaged tooth.



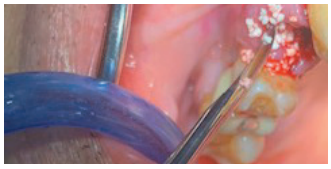
3. Placement of implant ISY+.



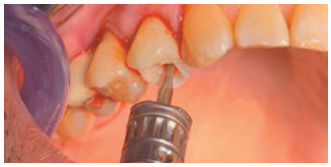
4. Primary stability higher than 45 Ncm.



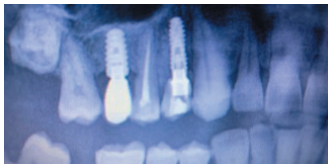
5. Bone graft with RIGENERA[BCP].



6. Rapid vascularization on the whole graft.



7. Placement of screw-retained crown.

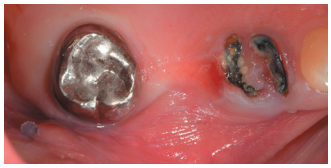


8. X-ray check after a year with a good radiopacity of the biomaterial.

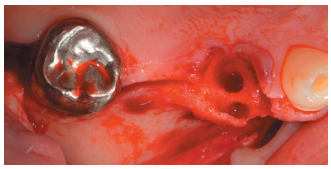
Courtesy of Dr. Vítor Vaz.

CASE 2: **GREAT MAXILLARY SINUS LIFT**
GRANULES 2.0g - 1.0-2.0 mm

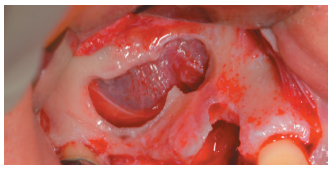
Male Patient, 58 years old, non-smoker.



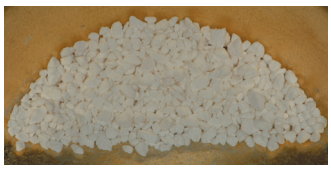
1. Maxillary bone atrophy.



2. Opening of surgical flaps.

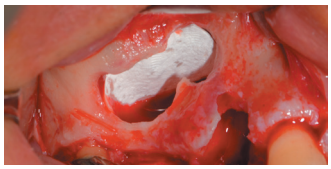


3. Osteotomy to access to maxillary sinus.



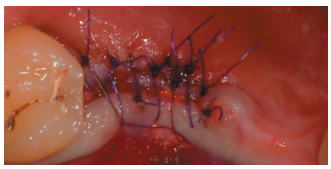
4. Filler preparation with RIGENERA[BCP].

5. Blending with patient's blood.



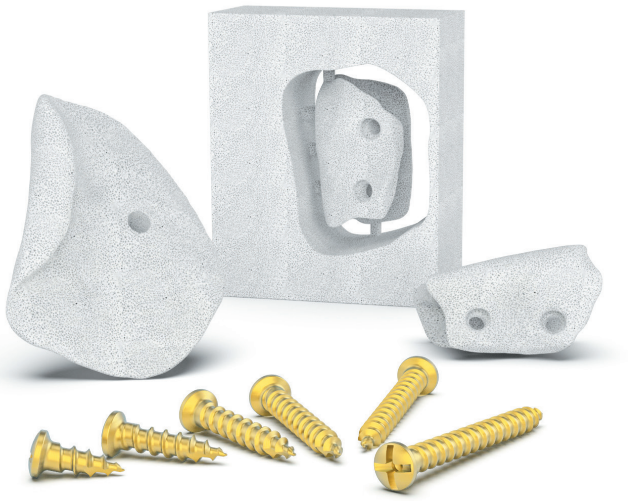
6. Membrane placement.

7. Intraoral picture of the filling with RIGENERA[BCP].



8. Suturing of surgical flaps.

Courtesy of Dr. Alessandro Cucchi.



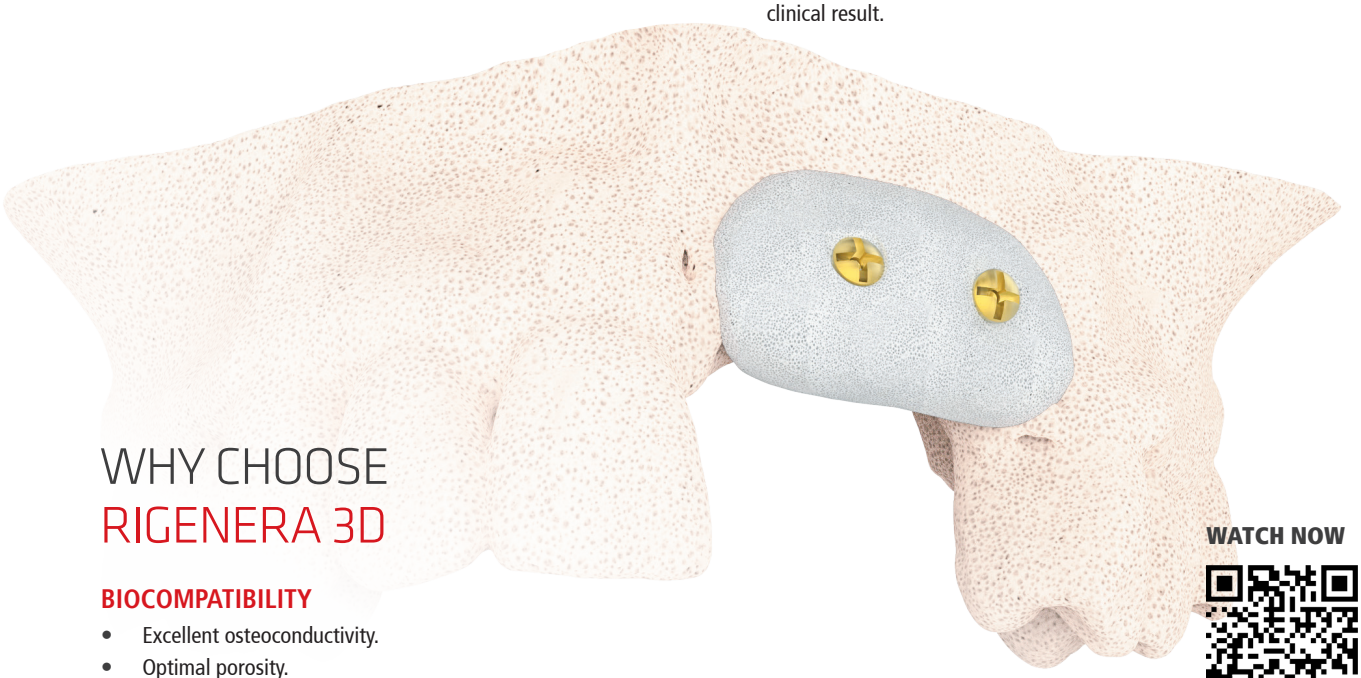
CUSTOMIZED BONE GRAFTS

RIGENERA 3D

The custom-made alternative to the anatomical modelling of bone grafts.

Fast reconstruction of the bone by means of an anatomical modelling of the bone graft.
RIGENERA 3D is designed virtually and for the specific patient using the most up-to-date CAD/CAM 3D technologies.

The perfect and precise three-dimensional fitting reduces dramatically the chair time of the whole surgery.
It makes useless the autologous bone grafting procedure and the manual adjustment of the block, thus reducing the morbility of the donating site in order to obtain a safe, reliable and predictable clinical result.



WHY CHOOSE RIGENERA 3D

BIOCOMPATIBILITY

- Excellent osteoconductivity.
- Optimal porosity.
- Highly hydrophilic properties.

MECHANICAL PERFORMANCES

- Controlled morphology.
- High resistance to mechanical stress during healing.
- High dimensional stability.

INNOVATION

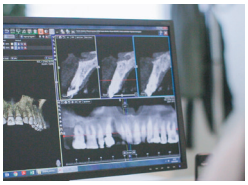
- Innovative digital process.
- Precise preoperative planning.
- Drastic reduction of intraoperative time.
- Traceability.
- Optimization of the interface between bone and graft.
- Verified process.
- Holes for cortical screws already present in the graft.

WATCH NOW

PICTURE	TYPOLOGY	DIMENSION	CODE
	MINI	**10x15x15 mm** (for small reconstructions)	C72BF20...
	MEDIUM	**24x22x15 mm** (for medium reconstructions)	C73BF20...

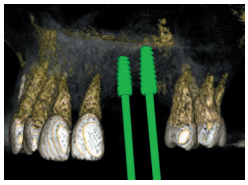
In addition to custom-made grafting, a BONE GRAFT REPLICA (code C71PE...) is made in biocompatible material (PEEK). On request, a resin BONE MODEL (code C42SP..., C45SP...) can also be product, by means of high resolution 3D printing.

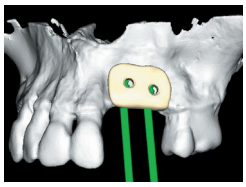
DIGITAL WORKFLOW
RIGENERA 3D



CONE BEAM CT AND PRODUCTION OF A 3D VIRTUAL BONE MODEL

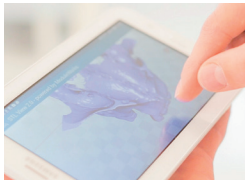
The fundamental requirement is a Cone Beam CT of the jaw, with a special focus on the area with the defect. The process starts with the acquisition of the patient's tomographic examination. **The DICOM file is sent by the clinician to the BTK TEAM using the Web, for the beginning of the design phase (http://upload.btk.dental/btk3d).**





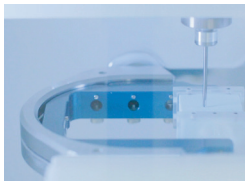
DIGITAL PROCESSING OF THE 3D-BONE STRUCTURE

Based on the patient's situation, the device is designed using the CAD modelling software within the framework of a fully digitalized work flow. **The morphological and dimensional features of the device** and the position of the holes for the cortical screws **are specifically designed so as to fit the patient's anatomy, while preserving the noble structures.**



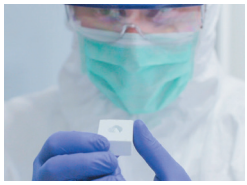
CHECK AND APPROVAL BY THE PRESCRIBING CLINICIAN

The clinician receives a three-dimensional digital model of the requested custom-made block, can check its compliance and authorize its production. Alternatively, the virtual graft is remodelled as needed until it is approved. To authorize production, the clinician sends a prescription of the custom-made device.



PRODUCTION OF THE GRAFT AND OF THE REPLICA

The graft is made out of a BTK synthetic bone block. It is produced by subtractive technology, using a dedicated machine for the biomaterial: an extremely precise multi-axis milling machine. At the same time, BTK produces the graft replica in biocompatible and autoclavable material.



CHECKING, PACKAGING AND STERILIZATION

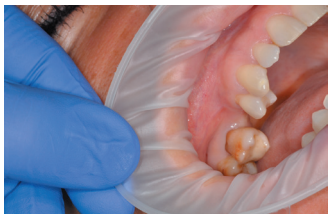
Upon completion of the manufacturing phase, production standards are carefully checked by means of conformity controls, followed by decontamination by means of ultrasonic baths in an automatic washing machine and subsequent packaging in a clean room. The product is supplied ready to be sterilized by the doctor.

http://upload.btk.dental/btk3d

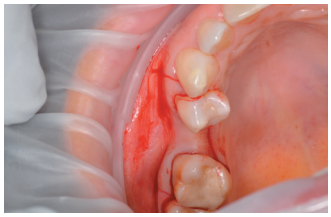
Immediate uploading of the DICOM file of the patient's tomography.

For more INFO write to: btk3d@btk.dental

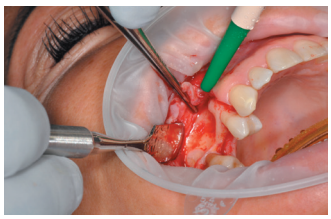
SURGICAL PROCEDURE



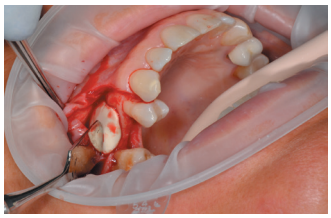
1. Deep bone reabsorption which makes impossible the placement of dental implants.
Anestesia and preparation of the surgical field.



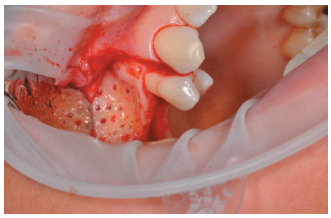
2. Soft tissues incision.



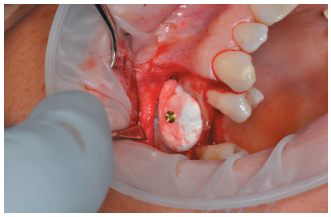
3. Opening flaps.



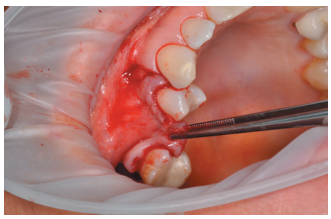
4. The replica made in PEEK is positioned and the holes for the placement of cortical screws are made.



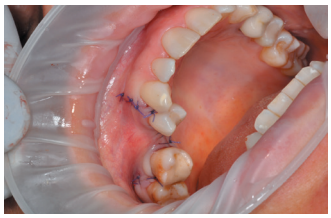
5. Preparation of the receiving bed.



6. The bone graft is fixed in the vestibular side with a proper cortical screw.



7. Closing of the flaps.



8. Suturing.
The bone graft remains 10 months prior to proceed with the second surgical step with implant placement, according to the surgeon's preferences.

Courtesy of Dr. Michele Augello.

REPLICA OF THE GRAFT MADE OF BIOCOMPATIBLE MATERIAL

In addition to the custom-made bone graft, we deliver a **replica** made of **PEEK**, a biocompatible and autoclavable material.
It is a copy of the graft and already has the holes for the cortical screws.

It is very useful in the first surgical phases:
1. Simulation of the surgery on the model, before performing actual surgery.
2. Correct management of flaps and soft tissues.
3. Checking of the fitting.
4. Surgical guide for drills, to make the holes for the cortical screws.

SURGICAL KIT BT-SCREW

Fixation screw kit for advanced surgery

RIGENERA APPLICATIONS

APPLICATIONS			PERIODONTAL DEFECTS	CYSTS AND ORAL CAVITIES	LARGE CYST AND SINUS LIFT	OSTEOTOMY	BONE DEFECTS
NAME	DIMENSION	CODE					
RIGENERA^{BCP} (IN GRANULES)	0.25 - 1.0 mm	704NA005	✓	✓	✓	–	–
	1.0 - 2.0 mm	704NA020	–	–	✓	✓	✓
RIGENERA 3D (CUSTOMIZED BONE GRAFTS)	MINI 10x15x15 mm	C72BF20...	–	–	✓	✓	✓
	MEDIUM 24x22x15 mm	C73BF20...	–	–	–	–	✓

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IN GRANULES.

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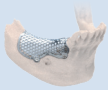

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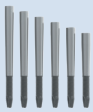

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The pterigoid solution.

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