

DIGITAL DENTISTRY
CUSTOM-MADE MEDICAL DEVICES



CUSTOMIZED
BONE GRAFTS

3D-BONE

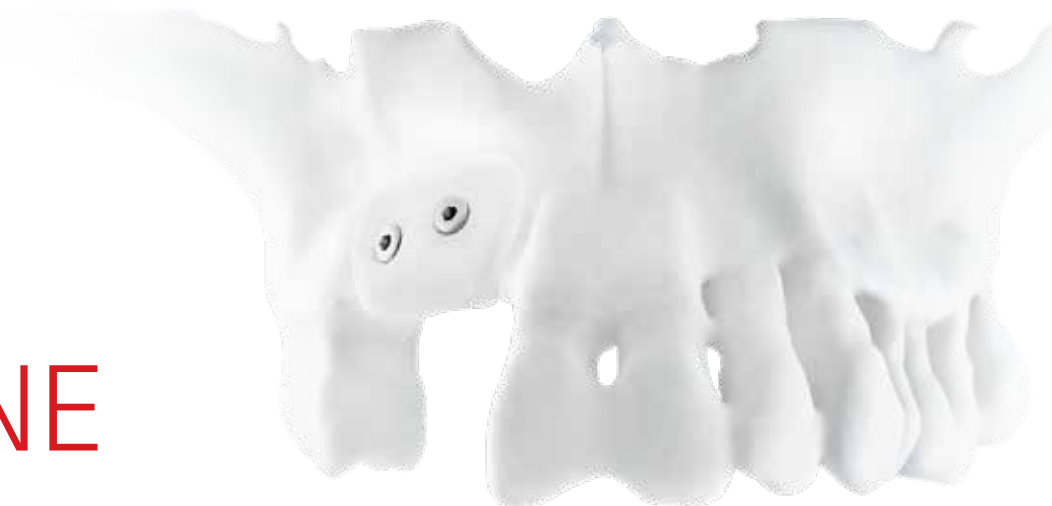


THE NEW DIGITAL FRONTIER
IN REGENERATIVE AND RECONSTRUCTIVE
BONE SURGERY

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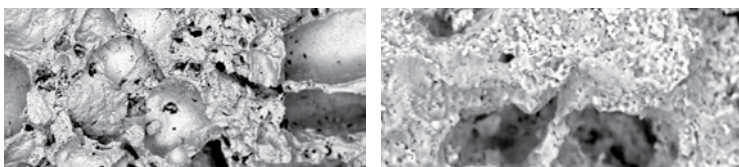
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CUSTOMIZED BONE GRAFTS 3D-BONE



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

The "3D-BONE" service offers to the clinicians not only innovative, preformed synthetic bone grafts, modelled with utmost precision based on the patient's bone defect, but also a complete work flow that simplifies surgical procedures and drastically reduces the duration of surgery.



Scanning electron microscope (SEM) images of the biomaterial (at various magnifications).

CHARACTERISTICS

1. Composition

The material has a biphasic composition.

- **70%** slow resorbing **hydroxyapatite (HA)** to preserve bone volume.

- **30%** fast resorbing **beta tricalcium phosphate** (β -TCP) to facilitate osseointegration.

2. 70% Porosity

The material features 2 different, interconnected POROSITIES.

- **MACRO 300-600 μ m**

- **MICRO 20 μ m**



This structure has been devised to favour osteogenic processes.

3. Compressive strength 10 MPa.

4. Highly hydrophilic.

INDICATIONS FOR USE

- Reconstructive and regenerative bone surgery
- Vertical regeneration
- Periodontal defects
- Peri-implant defects
- Sinus lift
- Cystic cavities
- Post-extraction cavities
- Crestal defects

PICTURE	TYPOLOGY	DIMENSION	CODE
	MINI	10x15x15 mm (for small reconstructions)	C72BF..
	MEDIUM	24x22x15mm (for medium reconstructions)	C73BF..

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.

WHY CHOOSE 3D-BONE

BIOCOMPATIBILITY

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

MECHANICAL PERFORMANCES

- Controlled morphology.
- High loading strength and high resistance to mechanical stress.
- High dimensional stability.

INNOVATION

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

SURGICAL PROCEDURE



1. Positioning of the PEEK replica and preparation of the cortical screw site



2. Positioning of the biomaterial graft



3. Fixing of the graft with the cortical screw



4. Graft fixed at vestibular level



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 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.

BT SCREW SURGICAL KIT

Fixation screw kit for advanced surgery.



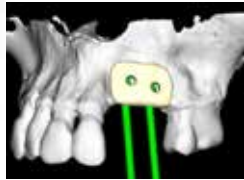
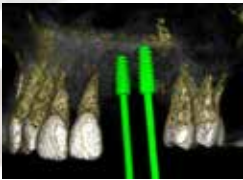
DIGITAL WORKFLOW

BTK 3D-BONE



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 material.



CHECKING, PACKAGING AND STERILIZATION

Upon completion of the manufacturing phase, production standards are scrupulously checked by means of compliance tests. Then the device is cleaned in an ultrasonic automatic machine and packed in a clean room under controlled atmosphere. The product is sterilized by means of GAMMA RAYS following a validated sterilization process.

<http://upload.btk.dental/btk3d>

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



For more INFO write to: btk3d@btk.dental

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CUSTOMIZED BONE GRAFTS

The new digital frontier in bone regeneration surgery.

3D-BONE is the rapid and reliable solution for effective bone integration.

Based on the patient's CBCT, the bone graft is produced using CAD-CAM technology. It can be used for small and medium sized bone reconstructions and to prepare the site for receiving one or more dental implants needed to replace missing teeth.

100% DIGITAL, 100% CUSTOMIZED.

IT MEETS THE EXPECTATIONS OF CLINICIANS AND PATIENTS.

STATE OF THE ART PRECISION AND CUSTOMIZATION.

REDUCED
SURGICAL TIMES

REDUCED
SURGICAL RISKS

PERFECT
ANATOMIC
CONFORMATION

TECHNICAL
SUPPORT

DEDICATED
SURGICAL KIT
WITH CORTICAL
SCREWS

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BTK PERSONAL TUTOR

A program for individual case planning and execution supported by experienced professionals in order to leverage know-how and maximize clinical experience with the aim to achieve sustainable high patient satisfaction rates.

BTK is always at your disposal for any request for further follow-up or information, promoting periodic and ad-hoc training course.

CERTIFIED QUALITY SYSTEM

**BIOTEC is certified UNI EN ISO 9001
and UNI EN ISO 13485.**

Custom-made device, in accordance with Directive 93/42/EEC and subsequent modifications and additions.

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

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.