maxresorb® &
maxresorb® inject
Innovative bi-phasic calcium phosphate
Scientific and clinical evidence
Dr. Georg Bayer, Dr. Frank Kistler, Dr. Steffen Kistler,
PD Dr. Jörg Neugebauer et al.

Hard tissue
synthetic
resorbable
safe
The dental clinic in Landsberg

Dr. Georg Bayer, Dr. Frank Kistler, Dr. Steffen Kistler, PD Dr. Jörg Neugebauer

Team Landsberg
The dental clinic in Landsberg is situated in the holiday area by the foothills of the Alps. It exists for more than 30 years. At the moment there are eight colleagues working there, specialized in different fields of dental medicine.

Two different DVT devices with various volumetric capacity enable the most modern pre- and postoperative diagnostics for diverse augmentative procedures. Besides their clinical work the members of the team in Landsberg are nationally and internationally in demand as speakers and frequently give an account of their experiences in publications.

Dr. Georg Bayer
Founder of the clinic in 1981
Limited to dental treatment for implant procedures
1973-1978 Dental education University Berlin
since 1996 ICOI Diplomate (International Congress of Oral Implantologists)
since 2007 Ambassador Status of the International Congress of Oral Implantologists (ICOI)
since 2004 Founding member of DGOI
since 2009 President of DGOI, German Section of ICOI

Dr. Frank Kistler
Managing Director of private dental clinic
Center of interest: aesthetic and functional rehabilitation
1990 – 1995 Dental education University Berlin and Munich
1995 – 1999 Postgraduate specialization in Prosthetics, University Munich
since 2004 ICOI Diplomate (International Congress of Oral Implantologists)
since 2004 Founding member of DGOI
since 2009 Specialist for Implantology (European Dental Association (EDA))

Dr. Steffen Kistler
Managing Director of private dental clinic
Center of interest: complex surgical and prosthetic rehabilitation
1990 – 1995 Dental education University Berlin and Munich
since 2000 ICOI Diplomate (International Congress of Oral Implantologists)
since 2004 Founding member of DGOI

PD Dr. Jörg Neugebauer
Scientific Director of the clinic
Center of interest: advanced surgical techniques
1984 – 1989 Dental education University Heidelberg
1990 – 2001 Director R&D Friadent, Mannheim
2001 – 2004 Postgraduate specialization in Oral surgery, University Cologne
2004 – 2010 Consultant University Cologne
since 2009 Specialist for Implantology (EDA)
since 2010 Part time faculty University Cologne
since 2012 Chairman of Clin. Innovations Committee, Academy of Osseintegration, USA
Bone is a highly specialized tissue with properties strongly adapted to its supporting and skeletal function. Bones are composed of ~65% inorganic matrix, the mineral phase, and ~35% organic matrix.

The main component of the mineral bone phase (~90%) is hydroxyapatite (biological apatite). This inorganic part is responsible for the high stability of the bone. The organic matrix (collagen fibers) is the basis for the elasticity of the bone. Only an interaction of collagen fibers and bone minerals enables the flexibility and tensile strength of the bone.

Bone structure
Bones are constructed according to a lightweight principle; the structure enables a very high stability accompanied by a relatively low weight. The composition on the periphery is very solid (cortical bone, compacta), while the inner part is less densely structured with lattice-shaped bone trabeculae (cancellous bone).
Bone biology and remodeling communication of cells

Despite its high stability bone is in no way a rigid tissue, but is characterized by a high metabolism and is subject to constant remodeling. This dynamic is necessary to save the skeleton from degradation by the reparation of structural damages (micro fractures).

Furthermore, the continuing rebuilding serves to adapt the micro structure of the bone (direction and density of trabeculae) to changing loads. These adaptations are the reason for bone atrophy following missing load (e.g. atrophy of the jaw bone after tooth loss).

Three different types of bone cells contribute to bone remodeling. The degradation of old bone matrix is carried out by osteoclasts. In the course of this process so called resorption lacunae are built that afterwards are filled with new bone matrix by cells called osteoblasts. The osteoblasts are sealed by the mineralization of the extracellular matrix. These mature bone cells that are no longer able to produce osteoid are called osteocytes. Osteocytes are involved in the formation and restructuring of the bone and are therefore important for maintaining the bone matrix.

Bone remodeling

Balance between bone degradation by osteoclasts and bone formation by osteoblasts.
Bone and Regeneration Techniques

The use of bone graft materials

Bone graft materials are applied to replace and regenerate bone matrix lost by various reasons such as tooth extraction, cystectomy or bone atrophy following loss of teeth or inflammatory processes.

For the filling of bone defects the patient's own (autologous) bone is considered the „gold standard“, because of its biological activity due to vital cells and growth factors. Nevertheless, the harvesting of autologous bone requires a second surgical site associated with an additional bony defect and potential donor site morbidity.

In addition, the quantity of autologous bone is limited. Today, due to a progressive development, bone graft materials provide a reliable and safe alternative to autologous bone grafts. Clinicians can choose between a variety of different bone graft materials and augmentation techniques. Bone graft materials are classified by their origin into four groups.

The GBR/GTR technique

The principle of Guided Bone Regeneration (GBR) or Guided Tissue Regeneration (GTR) is based on the separation of the grafted site from the surrounding soft tissue by application of a barrier membrane. Collagen membranes act as a resorbable matrix to avoid the ingrowth of the faster proliferating fibroblasts and/or epithelium into the defect and to maintain the space for controlled regeneration of bone.

The application of bone graft material into the defect prevents the collapse of the collagen membrane, acting as a place holder for the regenerating bone and as an osteoconductive scaffold for the ingrowth of blood vessels and bone forming cells.

Classification

Autologous:
- patients own bone, mostly harvested intraorally or from the iliac crest
- intrinsic biological activity

Allogenic:
- bone from human donors (cadaver bone or femoral heads of living donors)
- natural bone composition and structure

Xenogenic:
- from other organisms, mainly bovine origin
- Long term volume stability

Alloplastic:
- synthetically produced, preferably calcium phosphate ceramics
- no risk of disease transmission

For large defects a mixture of autologous or allogenic bone with high biological potential, and a bone graft material for volume stability of the grafting site, is recommended.


The benefit of calcium phosphate ceramics as bone regeneration materials was realized long ago, as they are the main component of bones and therefore provide an excellent biocompatibility without any foreign body reactions.

In contrast with the first solely bioinert biomaterials, the advantages of calcium phosphates are their bioactive properties as well as their resorbability. Calcium phosphates support the attachment and proliferation of bone cells and undergo a natural remodeling process that includes osteoblasts and osteoclasts and that is characterized by an initial integration of the material into the surrounding bone matrix and a gradual degradation. Among the calcium phosphates, hydroxyapatite (HA), alpha-tricalcium phosphate (α-TCP) and beta-tricalcium phosphate (β-TCP) have the most widespread use as bioceramics. Compared to all other calcium phosphates, hydroxyapatite shows the slowest solubility, therefore providing the highest stability. By contrast, the alkaline β-TCP demonstrates a higher solubility and thereby fast resorption kinetics.

An ideal bone regeneration material should be resorbed in pace with new bone matrix formation. The basic principle of the biphasic calcium phosphates is a balance between the stable hydroxyapatite, which can be found years after the implantation, and the fast resorbing β-TCP. Bone regeneration materials based on mixtures of HA and β-TCP have successfully been applied in dental regenerative surgery for more than 20 years.

**Hydroxyapatite (HA)**
\[ Ca_{10}(PO_4)_6(OH)_2 \]

**β-tricalcium phosphate (β-TCP)**
\[ Ca_3(PO_4)_2 \]
The ideal composition – bi-phasic calcium phosphates

The resorption properties of bi-phasic calcium phosphates can be changed by varying the mixing ratio of HA and β-TCP. A HA/β-TCP ratio between 65:35 and 55:45 has been proven particularly suitable in many studies\textsuperscript{3,4} and offers a controlled resorption with parallel bone formation\textsuperscript{5,6}.

Injectable calcium phosphates – cements and putties

Bone regeneration materials based on calcium phosphates are available in powder, granules and as porous blocks. The development of injectable bone regeneration materials started with the discovery of calcium cements in the 90’s\textsuperscript{7}. Cements result from the mixing of calcium phosphate powder with an aqueous solution. Following application, the hardening occurs in vivo. Cements create the possibility for several minimal invasive therapies of bony defects and offer an easier handling in many indications. The main disadvantage of the calcium phosphate cements is the reduced vascularization and natural remodeling experienced due to the stiffness and lack of interconnecting pores within the polymerised matrix. By mixing calcium phosphate granules with a water-based gel made of nano/micro hydroxyapatite granules (nano/micro HA) a moldable and non-hardening bone paste (putty) can be created. An example of such a non-hardening putty is maxresorb\textsuperscript{®} inject.

Putties offer two significant advantages over cements: First, their increased porosity allow for the ingrowth of blood vessels and bone tissue, resulting in a fast and complete integration into new bone matrix and a rapid natural remodeling. Second, due to their large surface area, the nano/micro HA particles exhibit a high biologic activity resulting in an osteostimulative effect of these putties. Nano/micro HA particles support the adhesion of bone cells and thereby a fast formation of new bone as well as a fast particle degradation, offering additional space for the ingrowth of bone tissue.

Calcium

- alkaline earth metal
- one of the most common elements
- essential mineral for humans
- important for regulation of metabolism
- besides phosphate, the main component of bone

\textsuperscript{3} O. Gauthier, J. M. Bouler, E. Aguado; Elaboration conditions influence physicochemical properties and in vivo bioactivity of macroporous biphasic calcium phosphate ceramics; J. Mat. Sci: Mat in Medicine 10 (1999) 199-204
\textsuperscript{5} G. Daculsi; Biphasic calcium phosphate concept applied to artificial bone, implant coating and injectable bone substitute; Biomaterial 19 (1998) 1472-1476
\textsuperscript{7} Brown WE, Chow LC (1985) Dental restorative cement pastes. In: US Patent 4'518'430, American Dental Association Health Foundation, USA
maxresorb® is an innovative, safe, reliable and fully synthetic bone graft substitute with improved controlled resorption properties and outstanding handling characteristics. The composition of 60% hydroxyapatite (HA) and 40% beta-tricalcium phosphate (β-TCP) results in two mineral phases of activity:

maxresorb® supports the formation of new vital bone, maintains the volume and gives mechanical stability over a long time period.

The osteoconductivity of maxresorb® is achieved by a matrix of interconnecting pores and a very high porosity of approx. 80%, as well as pore sizes from ~200 to 800 µm. The high macroporosity of maxresorb® is ideal for intense osteogenic cell growth and promotes the regeneration of vital bone. The high microporosity and surface roughness of maxresorb® facilitates diffusion of biological fluids and cell attachment.

The maxresorb® production process ensures a completely homogeneous distribution of the two calcium phosphate phases; resulting in high reproducibility. The unique maxresorb® production process leads to a highly nano-structured, bioactive rough surface for improved cell-adherence and hydrophilicity.

Properties of maxresorb®
- 100% synthetic
- safe, reliable & sterile
- bi-phasic homogenous composition
- completely resorbable
- very rough, hydrophilic surface
- ultra high interconnected porosity

Indications:
- Implantology,
- Periodontology,
- Oral Surgery & CMF
- Sinus lift
- Ridge augmentation
- Intraosseous defects
- Osseous defects
- Furcation defects
- Extraction sockets

maxresorb® – absolute safety and phase purity

Ceramic slurry
- Foaming
- Solidification / Drying

Porous ceramic body
- Granulation / Cutting
- Sintering > 1000°C
- Packaging / γ-Sterilization

Sterile product in double pouch

Safety by phase purity – x-ray spectroscopy of maxresorb®, Prof. Dr. C. Vogt, University of Hannover, all peaks can be assigned to HA (yellow) or β-TCP (green).
maxresorb® inject – Innovative Synthetic Injectable Bone Paste

maxresorb® inject is a unique and highly innovative, injectable bone graft paste, with controlled resorption properties.

The unique homogenous four-phasic composition of gel, active hydroxyapatite and granules of 60% HA/40% beta-TCP supports the formation of new vital bone, maintains volume, and is gradually replaced by new mature bone.

The highly viscous maxresorb® inject paste allows perfect shaping, molding, fitting and complete bonding to the surrounding bone surface of the defect. maxresorb® inject is a non-hardening synthetic bone paste.

Properties of maxresorb® inject
- injectable and easy handling
- viscous and moldable
- non-hardening
- optimal adaptation to surface contours
- active nano/micro HA particles

Indications:

- Implantology,
- Periodontology,
- Oral Surgery & CMF
- Sinus lift
- Intraosseous defects
- Extraction sockets
- Osseous defects
Biology as a model

Interconnected porosity

The unique production process leads to porous ceramics, resembling the structure of human cancellous bone with fully interconnected pores.

These interconnected pores are like tunnels within the material, providing access for fluids (blood) and also giving space and a surface for the ingrowth and migration of cells and blood vessels, thereby enabling the formation of new bone not only superficially but also inside the particles.

Rough surface – optimal condition for adhesion of cells and proteins

Beside safety, the advantage of synthetic materials lies in the reproducibility and ability to influence the structure. Due to a unique production process, maxresorb® has a very rough surface. This roughness is the basis for the osteostimulative effect often reported for calcium phosphates. Proteins, such as growth factors, adhere to the surface and support the bony regeneration. Moreover, the nano-structured surface promotes the adhesion of cells and also their final differentiation. Likewise, the excellent hydrophilicity of maxresorb® is based on its surface roughness. Blood is very quickly absorbed, and proteins (e.g. growth factors) from the blood adhere to the inner and outer particle surface, promoting regeneration and integration.

Meaning of the structure of bone regeneration materials

Macro – guidance
Rapid vascularization
Osteoconduction
Bone formation in pores

Micro - communication
Ingrowth of cells
Blood uptake by capillary effects

Nano - nutrition
Adhesion of cells, proteins (growth factors) and nutrients

Excellent blood uptake of maxresorb® and maxresorb® inject

Blood uptake of maxresorb® (hydrophilic surface)
In vitro research

Proliferation of osteoblasts on maxresorb®
PD Dr. Dr. D. Rothamel,
University of Cologne, Germany

The nano-structured surface of maxresorb® provides ideal conditions for the adhesion of osteoblasts. In vitro experiments demonstrated a fast proliferation of osteoblasts on maxresorb® granules.

After only 7 days a dense colonization of cells were observed. The improved attachment and proliferation of osteoblasts promote the osseous regeneration, resulting in a fast integration of the particles into the newly formed bone matrix.

Osteoblasts:
- small, mononuclear cells, of embryonic mesenchymal cell origin
- responsible for bone formation
- settle on bone and release a collagenuous basic substance (osteoid) into the intercellular space

Osteoclasts:
- multi-nuclear giant cells formed by fusion of mononuclear progenitor cells of the bone marrow
- main task is the resorption of bone substance by releasing protons (pH reduction) and proteolytic enzymes
Research with growth factors—
Adsorption and release of
growth factors from maxresorb®

In vitro experiments show that maxresorb® can be loaded with up to 6 mg BMP-2/g (A). A two-stage, controlled exponential release of bound growth factors (B) indicates that maxresorb® is especially suitable to support the osseous integration8.

Prof. Dr. H. Jennissen and Dr. M. Laub,
University of Duisburg-Essen/Morphoplant GmbH, Germany

Research with stem cells
maxresorb® supports the differentiation of stem cells
In vitro results from Prof. Dr. B. Zavan and Dr. E. Bressan, University of Padova, Italy

Collagen, osteopontin, osteonectin and osteocalcin are proteins that are expressed from progenitor cells after they start to differentiate into osteoblasts. All of these marker proteins could be detected 14 days after seeding of stem cells on maxresorb® granules, indicating the correct differentiation of the stem cells9.

* Zurinden K., Laub M., Dohle D.-S., Jennissen H.P.; Immobilization and Controlled Release of Vascular (VEGF) and Bone Growth Factors (BMP-2) on Bone Replacement Materials; Biomed Tech 2012; 57

Immunofluorescent staining of stem cells seeded on maxresorb®: red – osteopontin, green – osteocalcin
In vivo pre-clinical testing

Enhanced bone formation and controlled resorption of maxresorb®
Histomorphometric and degradation study of maxresorb®
PD Dr. J. L. Calvo-Guirado,
University of Murcia, Spain

Critical size defects were created in the tibia of rabbits and filled with maxresorb®. Nearly complete closure of the cortical defect after only 15 days. After 60 days, increase of medullary radio opacity, resembling cancellous bone.

Fast integration and natural remodeling of maxresorb® inject
In vivo results of maxresorb® inject for filling of femoral defects in rats,
Prof. Dr. R. Schnettler, University of Gießen, Germany

Only 3 weeks after implantation, particles are covered by a layer of new bone matrix. A close contact between both components of the material (β-TCP and HA) can be seen.

Active osteoblasts (right picture) and osteoclasts (left picture) on the surface of the HA as well as the β-TCP component.

The presence of these cells is a sign for the natural remodeling of maxresorb® inject, with a degradation by osteoclasts and formation of new bone matrix by osteoblasts.
Predictable results for sinus floor elevation with maxresorb®

Results of a sinus lift study from PD Dr. Dr. D. Rothamel, University of Cologne, Germany and Dr. D. Jelušić, University of Zagreb, Croatia

In a direct comparison with β-TCP in a clinically-controlled, randomized study with 20+20 patients for the indication of two-stage sinus floor elevation, the application of maxresorb® leads to highly predictable bone regeneration.

Following a healing phase of six months, biopsies from trephines taken at implant bed preparation demonstrated the osteoconductive properties of maxresorb®, supporting the formation of new bone matrix. 3D-radiological control images showed an excellent volume stability of the grafts, facilitating the insertion of the planned implants. No implant failures were observed in a first follow-up one year post-OP, emphasizing the safety and reliability of the bi-phasic material.
Clinical application of maxresorb®

Clinical case by Dr. Steffen Kistler

Sinus lift with two-stage implantation

DVT control after sinusitis surgery, residual bone height 1 mm

Transversal section to determine the depth of the sinus floor

Access to the sinus cavity by a lateral approach, minor perforation of the Schneiderian membrane

Covering of perforation with Jason® fleece

maxresorb® mixed with venous blood and collected bone chips

Augmentation of the sinus wall with a mixture of autologous bone and maxresorb®

Covering of the sinus window with collprotect® membrane fixed with two pins

Post-operative DVT control showing cavity between mucosa of the maxillary sinus and the membrane

Consolidation of graft material with minimal hyperplasia of sinus mucosa before implantation

Primary stable insertion of two implants after only 8 weeks

OPG control of implant insertion

Uncovering of implants 10 weeks post-OP

X-ray control after uncovering, showing dense regeneration of the graft material

Tip:
For easy application and optimal revascularization, the graft material should be mixed with blood collected from the defect, or with venous blood when larger volumes are needed.
Clinical application of maxresorb®

Clinical case by PD Dr. Neugebauer
Circular bone splitting in the upper jaw

3-dimensional implant planning with a radio-opaque scan template

Surgical presentation of the alveolar ridge with reduced amount of horizontal bone available

Deep bone splitting with oscillating saw in regio 15 to 25

Positioning of colpprotect® membrane for application of bone graft material

Lateral deposition of maxresorb® to prevent resorption of the vestibular wall

Covering of the augmentation site with the initially inserted membrane

Tight wound closure with a continuous seam following the periost splitting

Complication free healing of the augmented ridge

OPG control of inserted implants along the anterior sinus floor

Re-entry surgery in combination with vestibuloplasty to form the vestibulum

Soft tissue situation after healing with inserted abutments

Inserted bridge with terminally screwed and anteriorly cemented implants

Tip:
To achieve an even contour when stabilizing bone splitting in lateral augmentations, the smaller granules (0.5-1.0mm) should be used.
Clinical application of maxresorb®

Clinical case by Dr. Frank Kistler
Sinus floor elevation with simultaneous bone splitting and implantation

DVT image demonstrating horizontal and vertical amount of bone available

Reduced amount of bone on both sides of the upper jaw

Surgical presentation of the ridge with mobilization of the sinus mucosa through a lateral window

Splitting of the ridge after crestal osteotomy with bone condenser

Augmentation of the sinus cavity and fixation of the lateral wall with maxresorb®

Lateral augmentation with maxresorb® and osteotomy site with Jason® fleece

Covering of augmentation site with collprotect® membrane

Single sutures for tight wound closure after periost splitting

DVT image to control the inserted graft material

Control 3 months after augmentation of the alveolar ridge

Good consolidation of the bone graft material with wide alveolar ridge

Reduction of mucosal situation at re-entry surgery

Tip
For stabilization of bone splitting, a combined application of graft material and membrane shows the best long-term results.
Clinical application of maxresorb®

Clinical case by Dr. Georg Bayer

Lateral augmentation

DVT image showing the reduced amount of bone available in the area of the Foramen Mentale

Lateral bone defect following root tip resection

After preparation of the implant bed the thin vestibular wall is visible

Insertion of implant in the reduced bone amount

Lateral augmentation with maxresorb® and application of a dry collprotect® membrane

Complete covering of augmentation site and implant with the membrane

Wound closure by soft tissue expansion without vertical releasing incisions

Post-operative x-ray

Stable keratinized gingiva after insertion of healing abutment at re-entry

X-ray control at re-entry

Tip
For lateral augmentation with minimally invasive surgery, initial placement of a membrane and subsequent application of a graft material is advantageous.
Clinical application of maxresorb®

Clinical case by PD Dr. Jörg Neugebauer

Ridge reconstruction and sinus floor elevation

Tip
For sinus floor elevation, the large maxresorb® granules (particle size 0.8-1.5 mm) are especially suitable to gain sufficient space for osteogenesis and revascularization, even when larger volumes of the bone graft material are applied.

Defect after implant failure in regio 13, 14
Surgical presentation of the bone defect and thin alveolar ridge
Tension-free wound closure after vestibular incision
Implant insertion after 2 months

DVT showing the defect and caudalization of the maxillary sinus
Augmentation of the explantation defect with particulated bone
X-ray control of graft and ridge reconstruction
Control after implant uncovering

Sagittal section image to determine horizontal amount of bone available
Lateral augmentation with autologous bone plate and sinus floor elevation with maxresorb®
Horizontal presentation of the ridge reconstruction
Control of inserted locators in course of implant insertion in the upper jaw
Clinical application of maxresorb<sup>®</sup> inject

Clinical case by Dr. Frank Kistler

Internal sinus lift

Endodontically treated tooth 26 with apical cyst formation

X-ray control before implantation with partially regenerated extraction socket

Presentation of the soft tissue situation before implantation

Preparation of the implant bed for internal sinus lift with bone condenser

The maxresorb<sup>®</sup> inject paste is brought to instrument for application

Insertion of maxresorb<sup>®</sup> inject for internal sinus lift

Augmentation of the sinus floor by a crestal approach

Insertion of maxresorb<sup>®</sup> inject with bone condenser

Inserted implant before wound closure

X-ray control clearly showing the inserted maxresorb<sup>®</sup> inject

Tip

For internal sinus lift, the moldable graft material maxresorb<sup>®</sup> inject is ideally applied by a lateral approach as no further mixing with blood is needed.
Clinical application of maxresorb® inject

Clinical case from Dr. Damir Jelušić, Opatija, Croatia

Immediate implant installation

Extraction of the teeth, 14 and 15
Buccal dehiscence of the bone wall of tooth 14
Osteotome technique with insertion of maxresorb® inject (transalveolar) at tooth 15

Immediate implant insertion in extraction sockets of tooth 14 and 15
Placement of the healing abutments
Placement of Jason® membrane at the buccal bone wall

maxresorb® inject placed at buccal wall and protected by Jason® membrane
Wound closure and suturing
Post-op situation after 5 months of healing

3D CBCT 4 months post-OP
Situation after removal of healing abutments
Clinical view at control 1 year after surgery
# Product Specifications

## maxresorb® granules

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<td>0.8-1.5mm (L)</td>
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<td>20120</td>
<td>0.8-1.5mm (L)</td>
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## maxresorb® cylinders

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## maxresorb® blocks

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## maxresorb® inject

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