cerabone®
Natural bovine bone grafting material
Scientific and clinical evidence

natural
safe
pure
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 constant 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. 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 a bone graft material into the defect prevents a 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:
- Patient’s own bone, mostly harvested intraorally or from the iliac crest
- Intrinsically biological activity

Allogenic:
- Bone from human donors (multi-organ donors 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, which has excellent biological potential, and a bone graft material for volume stability of the grafting site, is recommended.
Xenogenic bone grafts are derived from animals, preferably of bovine origin. Bovine bone materials are deproteinized by heating (sintering) to minimize the risk of allergic reactions and disease transmission. Bovine bone materials have a long tradition, are very well documented, and their clinical application has found wide-ranging acceptance. The removal of all proteins transforms them into biologically derived hydroxyapatite ceramics. They are characterized by their preserved three-dimensional natural bone structure with interconnecting pores, strongly resembling the human bone structure. Their guided osseous integration rather than rapid resorption leads to excellent volume stability of the graft, with the formation of new bone on the highly structured bovine bone surface.

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cerabone® – natural bovine bone grafting material

cerabone® is derived from bovine bone in an established high-temperature heating process (sintering) guaranteeing high safety. Beside safety and reliability of the product and the production process, the material fulfills all other important requirements for the clinical success of a bovine bone graft material:

- Phase pure hydroxyapatite without organic components
- Rough and open porous structure comparable to native human bone
- Excellent hydrophilicity enabling a rapid uptake of blood
- Optimal biocompatibility proven in various in vitro and in vivo tests
- Rapid and controlled osseous integration

These characteristics are the base for the excellent clinical results of cerabone® demonstrated by high volume stability at the graft site, complete integration into newly formed bone matrix with high bone density.


Indications for cerabone®

Periodontology
- Intraosseous defects (1 - 3 walls)
- Furcation defects (class I - II)

Implantology and Oral and CMF Surgery
- Sinus floor elevation
- Horizontal augmentation
- Vertical augmentation
- Ridge preservation
- Peri-implant defects
- Socket preservation
- Bone defect augmentation

Product Specifications

cerabone® granules

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cerabone® block

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cerabone®: Safety and reliability facts made in Germany

Sintering
Heating up to 1250°C

Safety

cerabone® is made of cancellous bone from the femoral heads of domestic cattle. The processes of procurement and processing/production of this bovine material meet strict safety requirements. Thus the risk of BSE transmission can be considered negligible.

Patented manufacturing process
Both, product and process of procurement of the raw material as well as the production process are fulfilling the German and EU-regulatory and security requirements for bovine bone grafts including EN ISO 22442-1, -2 and -3, as well as Commission Regulation (EU) No 722/2012.
The proprietary manufacturing process of cerabone® is based on high-temperature heating (sintering) and special surface treatment that result in:
- Cell-friendly, biomimetically structured, rough surface
- Complete removal of organic components and albuminous impurities
- No risk of allergic reactions or rejection

CE marking
- CE certification of cerabone® was issued in 2002
- The product is on the market since January 2002

Sterile and storable
cerabone® is available as granules and in block form. The product is packed in sterile vials, sealed in primary and secondary blister packaging and sterilized with gamma irradiation. cerabone® can be stored at room temperature for up to three years.

cerabone®: 100% pure mineral bone phase

cerabone® consists of the pure mineral phase of bovine bone. No other phases besides hydroxyapatite are detectable. The high phase purity leads to maximal volume stability. In addition, the absence of organic components ensures the high safety of cerabone®.

Results from Prof. Dr. C. Vogt, University of Hannover

X-ray diffraetometry: mineral phases and crystallinity.
Narrow peaks and low baseline

cerabone® shows high crystallinity and 100% purity.

Infrared spectroscopy:
molecular fingerprint.
Characteristic peaks of phosphate and hydroxy groups of the hydroxyapatite
No other organic phases detectable.

Thermogravimetric analysis showing combustion of organic components.
No mass loss by heating cerabone® up to 1000°C
Complete removal of organic components (cells, collagen) by sintering process.

cerabone®
unsintered bovine bone graft

0.5 - 1.0 mm

0.5 - 1.0 mm

Particle size

ce Prof. C. Vogt, Leibniz University Hannover, Protoco on the analysis of bone graft material, 2012.
cerabone® serves as an excellent matrix for bone regeneration

Growth of osteoblasts and osteoclasts on cerabone®
In vitro results from Prof. Dr. D. Rothamel, University of Düsseldorf and Dr. C. Reichert, University of Bonn

The rough surface also promotes the adhesion of serum proteins and cells onto the surface. Osteoblast-like cells quickly adhere to the cerabone® particles. Only attached osteoblasts can start to produce new bone matrix leading to the osseous integration of the cerabone® particles. In another study, good adherence of osteoclasts promoted the superficial remodeling of the particles.

Proliferation of osteoblasts on cerabone®

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Bone biology: Scientific results from in vitro experiments

Colonization of cerabone® by osteoblasts
Prof. Dr. D. Rothamel

BMP-2 structure

Bound rhBMP-2 (mg/g cerabone®)

sustained release phase: half-life 35 days
burst phase: half-life 1 day

Loading capacity for BMP-2 (n=3, mean ± SD)

Two-phase controlled exponential release of BMP-2 may provide cerabone® with enhanced osseointegration (Morphoplant GmbH; patent application WO 2009/058667).

cerabone® and growth factors

in vitro experiments from Prof. Dr. H. Jennissen und Dr. M. Laub
University of Duisburg-Essen/Morphoplant GmbH

Growth of osteoblasts and osteoclasts on cerabone®
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Topography and hydrophilicity as key success factors

Optimal adhesion and ingrowth of cells, proteins and blood vessels

Excellent hydrophilicity of cerabone®

cerabone®’s rapid and complete hydration with blood or saline solution is crucial for superior handling characteristics, new bone formation and for the final clinical success.

Its strong capillary action facilitates fast and efficient penetration of the material particles with fluids, nutrients and blood through the three-dimensional, porous trabecular bone network, resulting in excellent handling, reliability and predictability in the daily clinical use.

The macroporous structure enables migration of cells, penetration of blood vessels and integration of the particles.

The capillary effect of the macroporous structure leads to a quick blood uptake of the material.

The rough surface ensures an excellent and homogeneous surface adhesion of cells and proteins.

Excellent hydrophilicity and fast blood uptake of cerabone®

Good hydrophilicity and fast blood uptake of cerabone®

Hydrophilicity of a non sintered bovine bone graft material

References:
Stem cell research

Interaction of cerabone® with stem cells
In vitro results from Prof. Dr. B. Zavan, University of Padova. cerabone® supports the differentiation of attached stem cells into osteoblasts that produce new bone matrix. Collagen, osteopontin, osteonectin and osteocalcin are proteins of the extracellular bone matrix that can be used as markers for bone formation. Their detection 14 days after seeding stem cells on cerabone® indicate the correct differentiation of the cells.

Tissue integration and cellular degradation
In vivo data from a mouse model by Dr. S. Ghanaati, University of Mainz and University of Frankfurt a. M.
15 days after implantation into the subcutaneous tissue (CT) of mice, cerabone® (CB) is embedded within a well vascularized granulation tissue (blood vessels marked by arrows). No fibrous encapsulation or inflammatory reactions are observed. Mononuclear and multinuclear cells (arrow heads) indicate the onset of cellular degradation of the cerabone® particles.

Maximal stability and good osseous integration of cerabone®

Histological studies on cerabone®

Compressive force (N) 1670±120 4510±770
Compressive resistance (N/cm²) 420±32 564±96
Shear force (N/cm²) 124±35 336±200

Optimal bone regenration after bone defect treatment with cerabone® was demonstrated in an animal study. Bony defects following apicoectomy, were filled with cerabone®. The histological examination showed a complete bridging of the osteotomy orifice after three months and a well established new bone (NB) and cementum formation (CEM) around the cerabone® particles.

Implantology

cerabone® – osseous integration and optimal stability
Sinus lift study from Prof. Dr. D. Rothamel, University of Düsseldorf

A study on 12 patients showed that cerabone® acts as an osteoconductive material that supports the regeneration of bone after sinus floor elevation surgery. After six months the particles of all biopsies were completely integrated into the newly formed bone matrix, while the grafted area showed excellent volume stability.

Endodontics

cerabone® – osteoconduction and bony regeneration

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Clinical application of cerabone®

Clinical case by
Dr. Marius Steigmann, Neckargemünd, Germany

cerabone® for coverage of implant dehiscence and ridge augmentation

Extraction of tooth 21 after endodontic treatment

Application of collacone® for stabilization of the blood clot

Buccal bone defect after eight weeks healing time

A periodontal probe demonstrates the vertical extension of the defect

Implant placed into the former extraction socket

Surface of the implant is covered with autologous bone

Coverage of the autologous bone with cerabone® (0.5 - 1.0 mm)

Covering of the bone substitute with Jason® membrane

Closure of the site using single sutures after periosteum slitting

Tension-free suturing maintains undisturbed healing

Abutment installation after implant uncovering, six months after implantation

Final prosthetic restoration with a full-ceramic crown

Contour maintenance
For augmentations in the aesthetic region cerabone® provides long-term dimensional stability and therefore a good bone bed to support an optimal contour of the soft tissue and sustained aesthetic result.

Rehydration
Due to its excellent hydrophilicity, cerabone® particles adhere to each other after mixing with blood or sterile saline solution, allowing optimal handling and good adaptation to surface contours.

Clinical application of cerabone®

Clinical case by
Dr. Viktor Kalenchuk, Chernivtsi, Ukraine

Ridge augmentation with cerabone® and collprotect® membrane

Clinical situation with narrow alveolar ridge in the lower jaw

3.5 mm dental implants inserted with inefficient immersion of dental implant platforms

Implants inserted and cortical bone perforated, vestibular view

Alveolar ridge form and size renewal around implants with cerabone®

cerabone® particles size 0.5 - 1.0 mm in place

Covering augmentation site with collprotect® membrane

Situation at re-entry six months post-operative, implants partly covered by new bone matrix

Implants uncovered, good integration of cerabone® particles

Particle Size
Small cerabone® particles (0.5 - 1.0 mm) allow a good adaption to surface contours; they are especially useful for lateral augmentations or to fill voids when working with autologous bone blocks.

For sinus lift and extensive augmentations the use of cerabone® particle size 1.0 - 2.0 mm is recommended. The increased space between the large particles enables a better vascularization and improves the regeneration of larger defects.
**Clinical application of cerabone®**

**Clinical case by**

Dr. Marius Steigmann, Neckargemünd, Germany

cerabone® for horizontal augmentation

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**Antibiotic prophylaxis**

Make sure that the patient’s blood contains a sufficient concentration of antibiotics before starting the augmentation (especially for larger augmentation volumes), e.g. by starting the antibiosis one day prior to surgery or at least one hour before by ingestion of a full daily dose.

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**Clinical case by**

Dr. Derk Siebers, Berlin, Germany

Socket management/ridge preservation with cerabone® and Jason® membrane

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Clinical application of cerabone®

Clinical case by
Prof. Dr. Dr. Daniel Rothamel, Düsseldorf, Germany

Two-stage sinus lift with cerabone® and Jason® membrane

Clinical situation before surgery
Surgical presentation of the atrophic alveolar ridge
Preparation of lateral sinus window
Filling of the sinus cavity with cerabone®

Additional lateral augmentation with cerabone®
Covering of the augmentation site with the slowly resorbing Jason® membrane
Tension-free wound closure
Detail of OPG showing radiopacity of cerabone®

Very good integration of cerabone® particles without soft tissue encapsulation
Implant placed in sufficient bone matrix
Trephine biopsy taken at implant insertion
Detail of the histology showing cerabone® particles covered by newly formed bone matrix

Schneiderian membrane perforation
In case of a small perforation (< 5 mm) of the Schneiderian membrane during sinus floor elevation, the application of a collagen membrane (e.g. Jason® membrane or collprotect® membrane) is a useful tool for perforation coverage. Instruct the patient to avoid sneezing for two weeks and prescribe antibiotics and swelling prophylaxis (e.g. xylometazoline). Never continue if you find an acute sinusitis with presence of pus.

Membrane coverage
For better and more predictable results we always recommend to cover the augmentation area (and the lateral sinus window after sinus floor elevation) with a collagen membrane (e.g. collprotect® membrane or Jason® membrane).

Clinical application of cerabone®

Clinical case by
Dr. Damir Jelušić, Opatija, Croatia

Sinus floor elevation with cerabone® and Jason® membrane

Pre-operative OPG
Preparation of a lateral window for sinus floor elevation
Perforation of the Schneiderian membrane visible after preparation of the lateral window
Jason® fleece introduced into the sinus cavity to cover the Schneiderian membrane

Filling of the sinus cavity with cerabone® (particle size 1.0 - 2.0 mm)
Simultaneous placement of three implants
Jason® fleece covering the lateral sinus window
Additional horizontal augmentation with cerabone® (particle size 1.0 - 2.0 mm)

Covering of the augmentation site with Jason® membrane
Re-opening six months after implantation, stable integration of the cerabone® particles
Placement of gingiva formers
Good situation after removal of gingiva formers, six weeks after re-opening
Clinical application of cerabone®

Clinical case by
Dr. Damir Jelušić, Opatija, Croatia

Socket preservation with cerabone®

- Pre-operative CT of teeth eleven and 21 after endodontic treatment
- Teeth eleven and 21 not worth saving and planned for extraction
- Situation after extraction of the front teeth
- Jason® membranes placed within in the extraction sockets, covering the vestibular wall
- Filling of the sockets with cerabone®
- Jason® membrane turned down over the socket and sutured
- Post-operative CT four months after extraction, good preservation of the ridge
- Flapless implant placement (punch technique) four months after socket preparation; complete integration of cerabone® particles
- Placement of gingiva formers
- Final prosthetic situation with individual emergence profile created with provisional crowns (Four months post implantation)
- Final prosthetic restoration with ceramic crowns

Density
Avoid to compress the cerabone® particles excessively at the defect site. Open space between the particles permits blood vessel ingrowth and the formation of new bone matrix.

Clinical application of cerabone®

Clinical case by
Dr. Raluca Cosgarea and Prof. Dr. Dr. Anton Sculean, Cluj-Napoca, Romania and Bern, Switzerland

Regeneration of intrabony defects with cerabone® and collprotect® membrane

- Pre-operative defect measurement
- Pre-operative x-ray showing intrabony defect
- Defect presentation after preparation of mucoperiosteal flap
- Rehydration of cerabone® particles
- Filling of intrabony defect with cerabone®
- Jason® membrane cut to shape
- Jason® membrane in place
- Wound closure
- X-ray control at 12 months post-operative
- X-ray at 24 months post-operative
- Final prosthetic restoration

Sterile application
Pay attention to sterile application of the substitute, e.g. by using new instruments for granule insertion (and trimming of membranes). Prior contact to saliva may contaminate your graft.