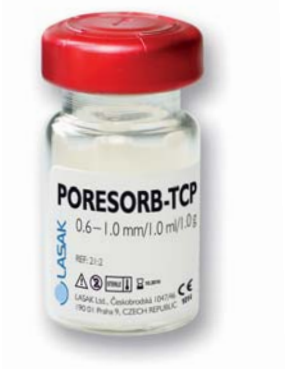
PORESORB®-TCP

Bone Regeneration Material

- Resorbability
- High phase purity
- Osteoconductivity
- High stability in defect



PORESORB®-TCP

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PHYSICOCHEMICAL PARAMETERS:

Composition: ß - tricalciumphosphate, $Ca_3(P0_4)_2$
Synthetic material - free of antigenic activity

Porosity: 30 - 40%

INDICATIONS:

implantology, periodontology

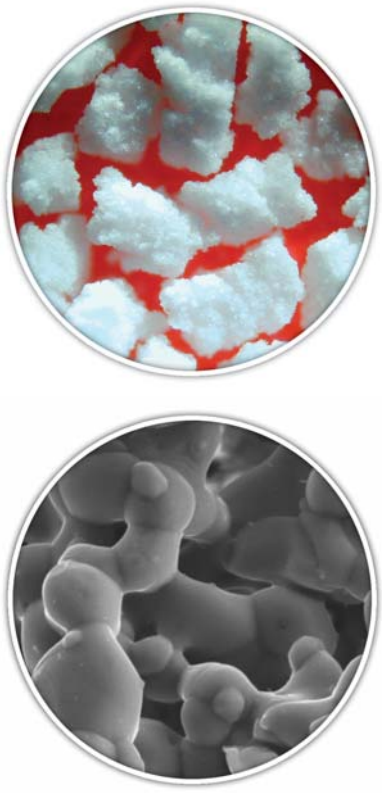
- Filling of bone defects after extirpation of cysts
- Treatment of periodontal defects
- Remodelling of the alveolar ridge
- Treatment of bone defects around dental implants
- Sinus lift
- Filling of bone defects after surgical extractions to prevent alveolar atrophy

orthopeadics, traumatology

- tumor-like lesions (unicameral bone cyst, aneurysmal bone cyst, bone gangliomas, fibrous dysplasia,...)
- pathological fractures with the above-mentioned lesions
- posttraumatic bone defects (comminuted osteoporotic fractures compressive fractures of a long bone epiphysis)
- benign bone tumors
- arthrodesis

ADVANTAGES:

- Resorbability
- High phase purity
- Osteoconductivity
- Highly safe material - no protein content, no risk of infection
- Interconnected pores
- Stable material in bone defects, with good workability



Structure of the PORESORB®-TCP
Granules are composed of micro-particles forming a network of interconnected pores.

For guided bone tissue regeneration it is recommended to cover the defect with a membrane (e.g. collagen or teflon) - to eliminate the migration of soft tissue cells into the surface layers of PORESORB®-TCP granules.

The material's structure is similar to that of bone, possessing two main sizes of porosity: macro-pores of approx. 100-200 μm in size and micro-pores ranging from 1 to 5 μm. Macro-pores provide sites for cell colonization and enable the ingrowth of bone into the centre of the defect. Micro-pores enable the fast penetration of blood and body fluids into the material and provide micro-rough surfaces favourable for protein and cell attachment. The material shows potentially osseoinductive properties i.e. it stimulates the differentiation of the mesenchymal cells towards osteoblasts, thus inducing new bone formation. In later stages of bone regeneration, due to hydrolysis and active phagocytosis, the material gradually disintegrates and is replaced by newly-formed bone tissue.
Micro porosity enables fast penetration of blood into the material, thus ensuring its excellent workability and stability (immobilization) in the defect.

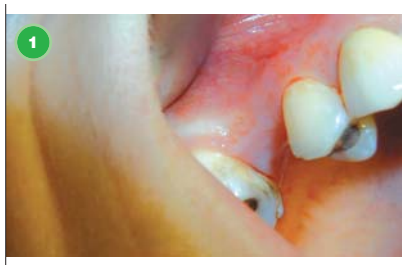
PRODUCTION PROCESS - QUALITY GUARANTEED

The material **PORESORB®-TCP** is manufactured under strict hygiene conditions, ensured by its periodic validation according to EU directive **91/356/EEC**. Raw materials are provided by permanent and renowned suppliers tested at accredited laboratories.

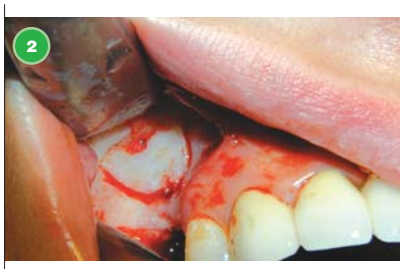
CLINICAL APPLICATION

SINUS LIFT PROCEDURE (LATERAL APPROACH)

The sinus-lift operation is an effective method which enables the use of dental implants in locations without sufficient alveolar bone volume. PORESORB®-TCP is inserted into the space of the maxillary sinus where dental implant fixation is enabled by new bone tissue formation.

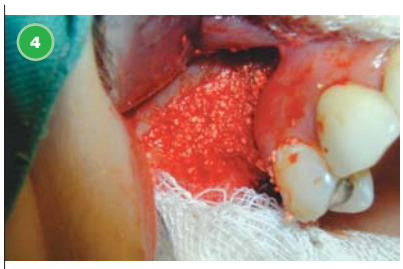


BEFORE OPERATION

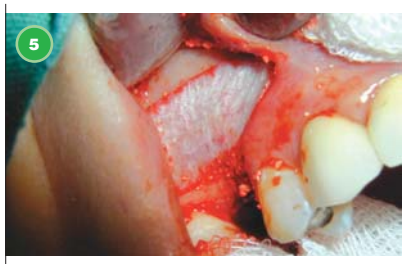


WINDOW CREATED IN THE FRONT SIDE OF THE MAXILLARY SINUS

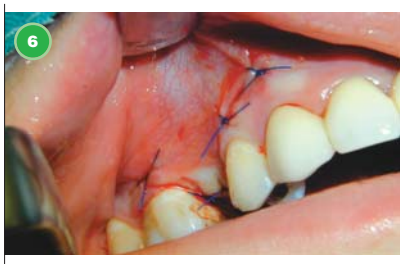
IMPLANT INSERTION



FILLING OF DEFECT WITH PORESORB®-TCP MATERIAL



DEFECT ISOLATION BY RESORBABLE MEMBRANE

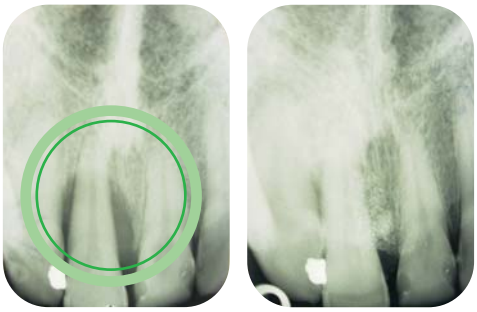


POST-OPERATIVE SITUATION

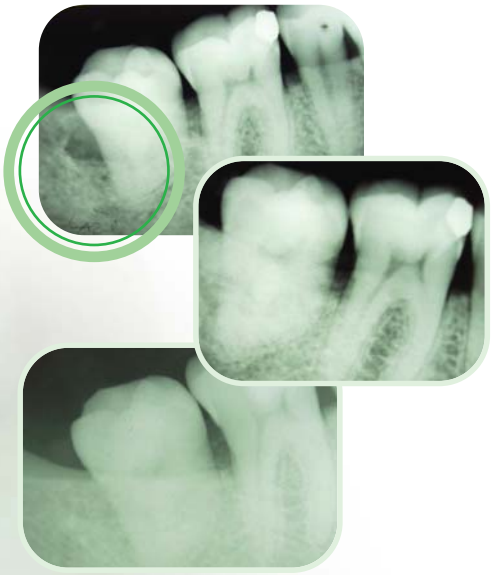
When PORESORB®-TCP is applied to the defect its micro-porous structure is a great advantage, ensuring excellent wetting by blood and giving high immobilization of the material in the defect. (Assoc. Prof. Josef Podstata, PhD, DrSc.)

Sterilization is electronically-controlled, and recorded, using internal indicators, and the sterility confirmed by testing at accredited laboratories. The product **PORESORB®-TCP** is in line with International Standard **ASTM F1088** (Standard Specification for Beta- Tricalcium Phosphate for Surgical Implantation), which requires a maximum content of trace elements of no more than 50 ppm and a phase purity greater than 95%. The **PORESORB®-TCP** has a phase purity up to 99.6%. Phase and chemical purity of each production batch is checked using X-ray diffraction and by chemical analysis.

TREATMENT OF PERIODONTAL DEFECTS

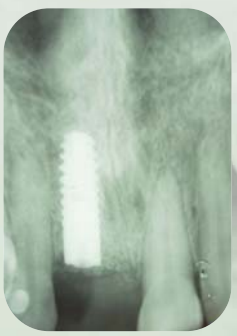


Treatment of intraalveolar defects (Periodontitis). Situation before and 6 months after treatment.



Periodontal defect before treatment, post-operation and 1 year after treatment. (Assoc.Prof. Pavel Poleník, MD, PhD.)

AUGMENTATION OF ATROPHIC ALVEOLAR RIDGE BEFORE DENTAL IMPLANT INSERTION

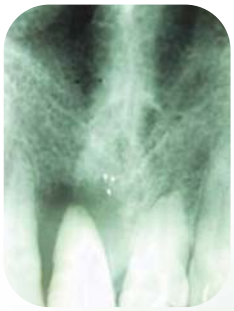


Resorbability of the material enables problem-free introduction of dental implant into the regenerated bone tissue, (implantation 1 year after treatment with PORESORB®-TCP). Assoc.Prof. Pavel Polenik, MD, PhD.

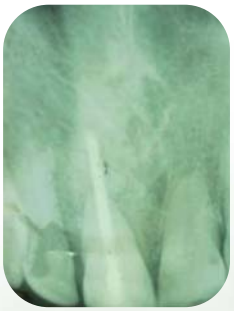
PORESORB®-TCP

THE USE OF PORESORB®-TCP IN COMBINATION WITH THE PLATELET CONCENTRATE (PRP) FOR THE REGENERATION OF PERIODONTAL AND BONE TISSUES

Regeneration of bone tissues at the place of periodontal defects depends on the presence and phenotypic expression of undifferentiated mesenchymal cells. Factors which stimulate these cells to regenerative activity can be obtained from the platelet concentrate (PRP) of the patient's blood. The combination of **PORESORB®-TCP** material with platelet concentrate results in a greater yield of bone tissue. No less important is its influence on the post-operative healing of adjacent tissues. Operation scars heal much faster which remarkably reduces the risk of post-operative infection.
The use of PRP in combination with **PORESORB®-TCP** as a suitable micro-porous carrier represents an accesible method for the intensification and speeding-up of processes of tissue regeneration.

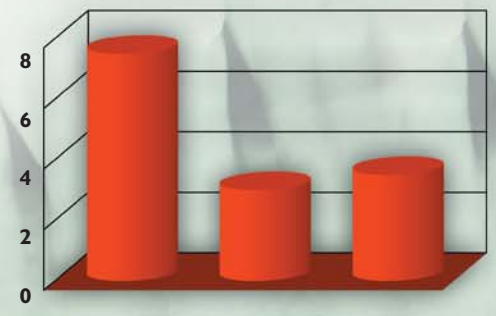


Extensive and advanced periodontal defect



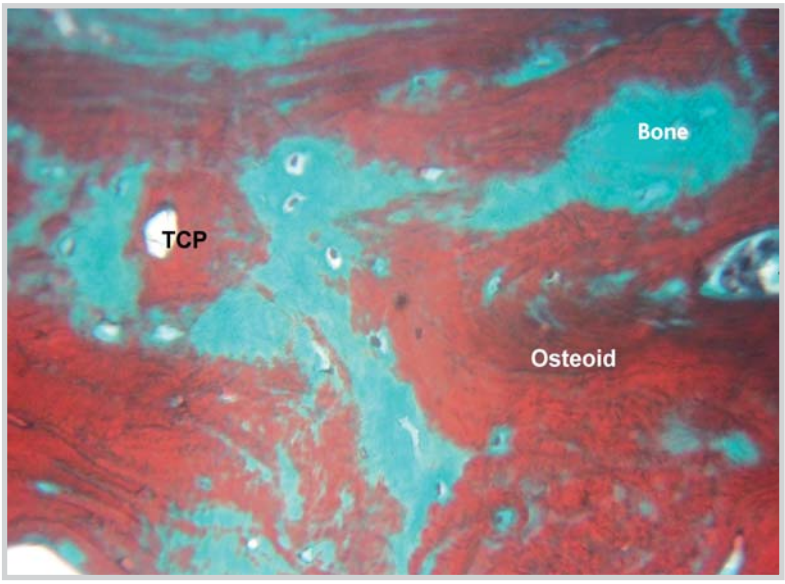
Situation 3 months after operation.
(Assoc.Prof. Pavel Polenik, MD, PhD.).

Depth of periodontal pockets

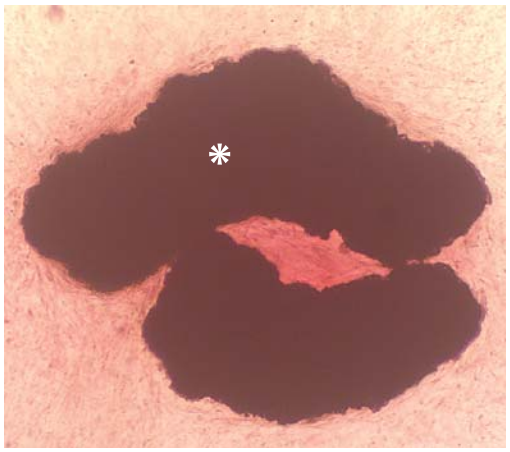


Before treatment **After 6 months** **After 12 months**

(Assoc. Prof. P. Polenik MD, PhD. et al., Clin. Oral. Impl. Res., Vol 14, 2004)

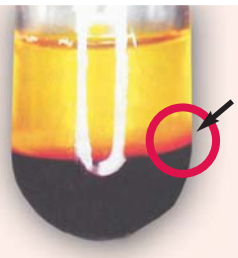


Histological undecalcified section of the **PORESORB®-TCP** material in a bone defect (dog tibia, 6 months and 5 weeks after treatment).
Resorption of the **PORESORB®-TCP** material takes place concurrently with the new bone formation until the material is completely replaced by bone.

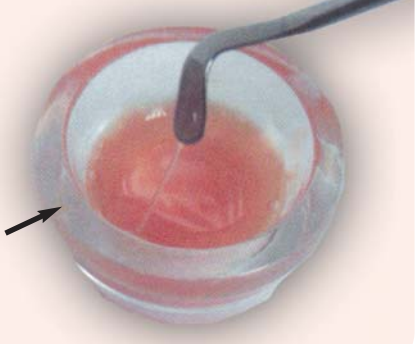


(MUDr. Z. Nathanský, CSc., et. al. Clin. Oral. Impla. Res, Vol. 14, 4,2003)

PORESORB®-TCP material(*) in the bone marrow cell culture after 10 days of cultivation. Positive (red) staining on alkaline phophatase enzyme indicates osteoblastic differentiation of the cells in contact with the material potentially osseoinductive property of the material.



Layer of centrifuged blood rich in platelets.



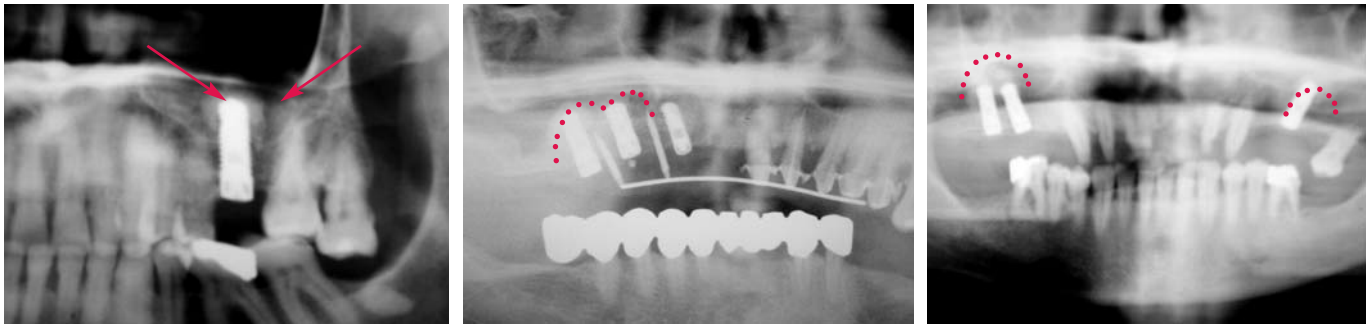
Gel created by PRP activation. In combination with **PORESORB®-TCP** material it creates an ideal composite material for the filling in of defects.

CLINICAL APPLICATION

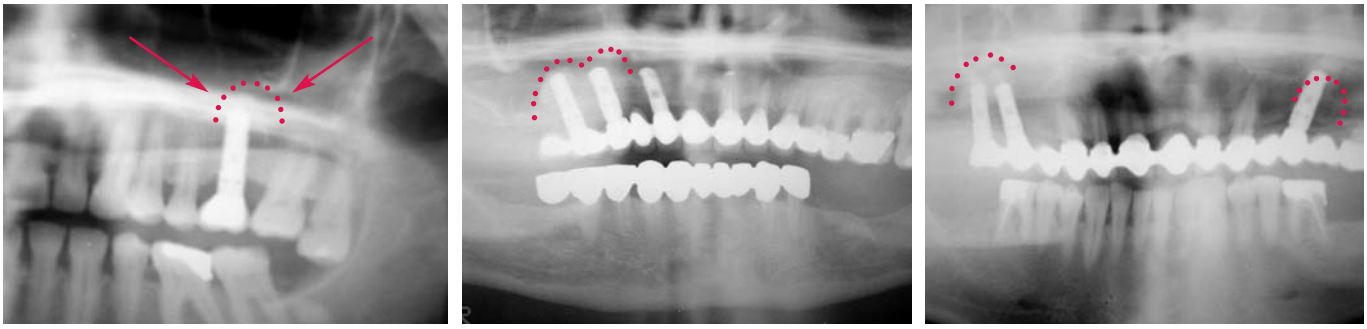
CLINICAL APPLICATION OF PORESORB®-TCP / SINUS LIFT PROCEDURE (INTERNAL)

Thanks to the high X-Ray contrast of the PORESORB®-TCP material, the process of resorption and bone tissue regeneration can be effectively monitored. The X-ray contrast becomes weaker as a result of the material's resorption and its replacement by bone tissue. The irregular polygonal shape of the granules ensures larger pore spaces and their lower immobility (high stability) in the defect.

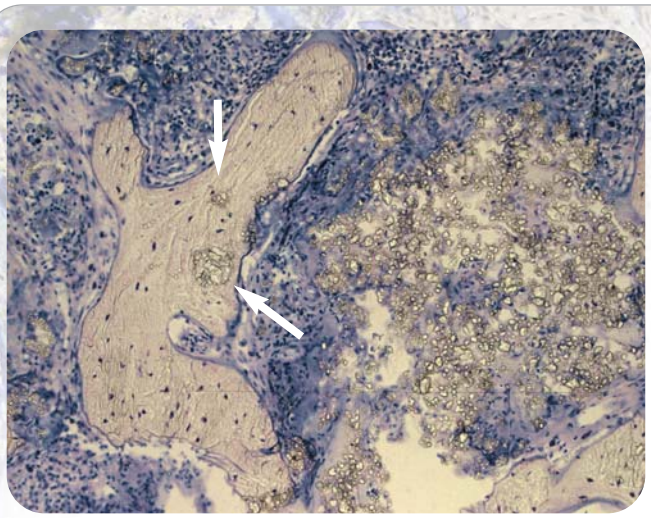
POST-TREATMENT



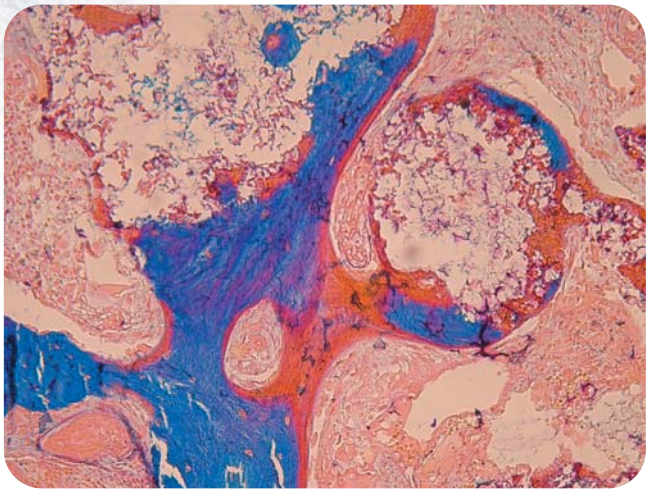
SITUATION TWO YEARS AFTER LOADING OF IMPLANTS



(Zdeněk Nathanský, MD, PhD.)



Histological examination of tissue removed during implantation into sinus-lift. Remaining particles of PORESORB®-TCP enclosed within the newly-regenerated bone are visible (Giemsa staining).



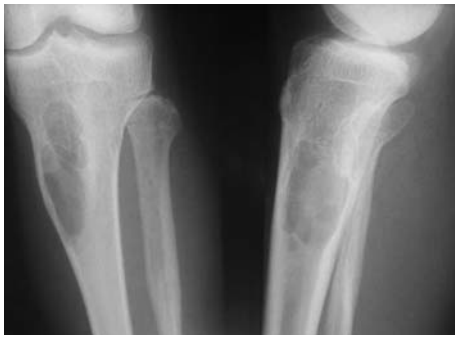
PORESORB®-TCP material surrounded by newly-regenerated bone tissue (mineralized tissue - blue; osteoid - red; Ladewig staining).

PORESORB®-TCP

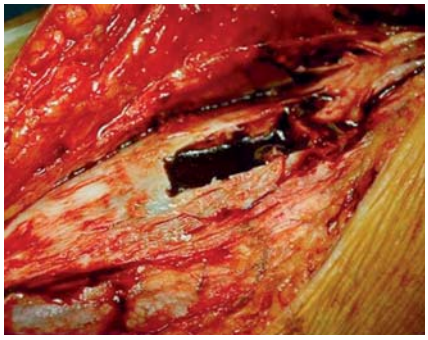
ORTHOPAEDICS AND TRAUMATOLOGY

PORESORB®-TCP may be applied either separately or in combination with autologous cancellous bone or autologous bone marrow.

CLINICAL CASES DOCUMENTED BY X-RAY



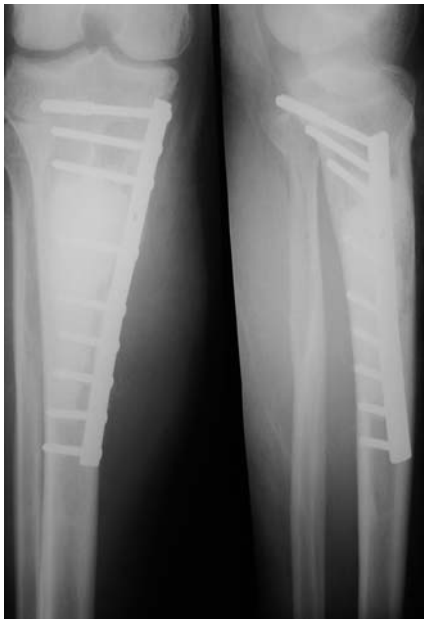
Preoperative X-ray image showing a large delineated defect in the proximal tibial metaphysis, reaching up to the diaphysis. The cause of the defect was fibrous dysplasia. The anterior part of the cortical bone is narrowed, while the other is adequately wide, and the defect is well delineated.



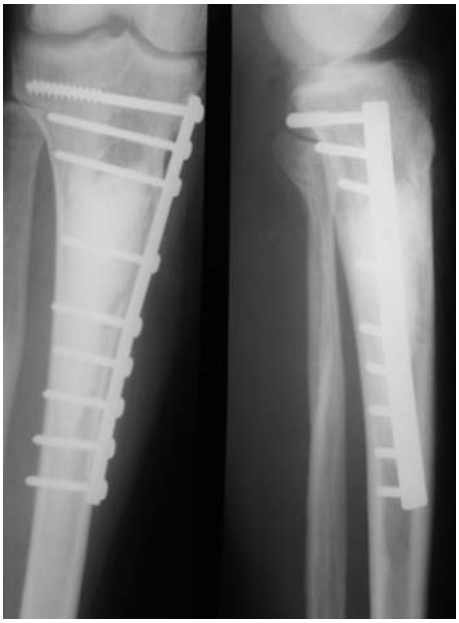
Operative approach from the anteromedial side; 6 x 1.5 cm trepanation window was distally extended during the surgery.

Mixing of PORESORB®-TCP with autologous bone marrow immediately before the application.

A defect filled with PORESORB®-TCP mixed with autologous bone marrow.



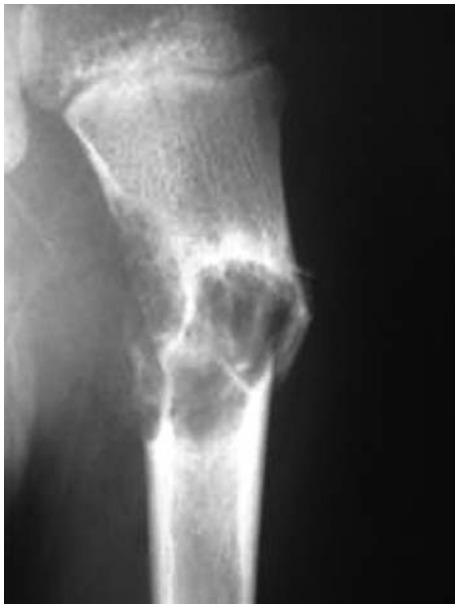
Postoperative X-rays. The AP projection shows residual fibrous dysplasia in the proximal part, while the remainder is filled completely. In the lateral projection, a long metallic plate fixed by screws is used to bridge the defect as a prevention of fracture until healing is complete.



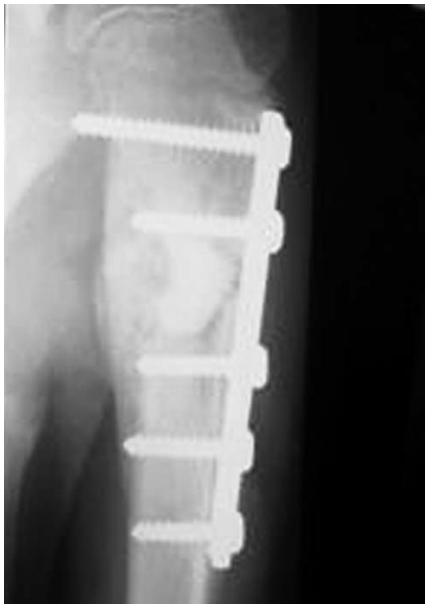
X-rays one month after surgery. The AP projection shows 24 x 15 mm residual defect, while the remainder is well filled. No reaction is seen around the metallic part or in the PORESORB®-TCP. No signs of resorption have been present so far.

CLINICAL APPLICATION

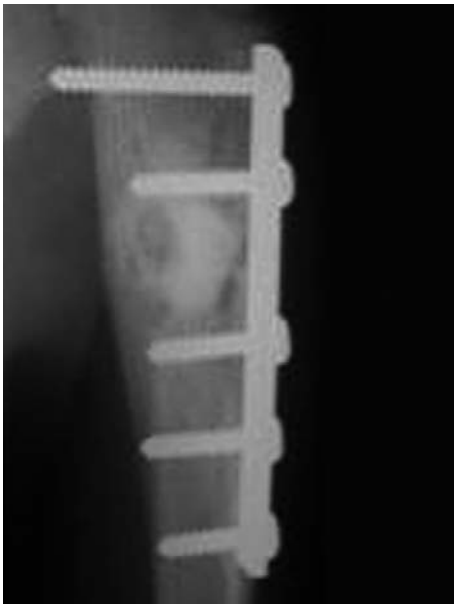
APPLICATION IN A BONE DEFECT WITH A PATOLOGICAL FRACTURE



A large cyst at the boundary of metaphysis and diaphysis of the humerus with a pathological fracture.

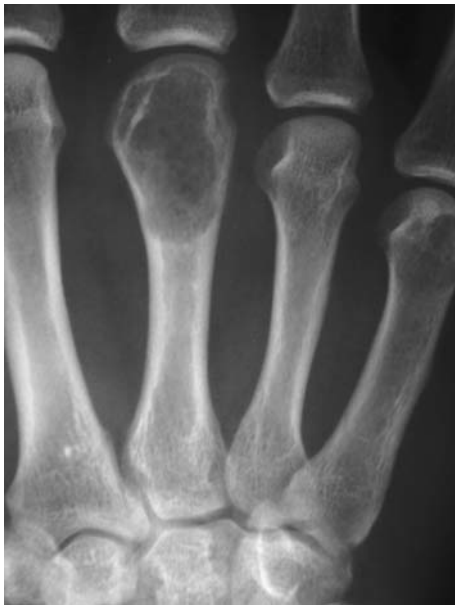


The fracture was repositioned, while the defect was filled with PORESORB®-TCP and bridged with a thin AO plate fixed by screws.

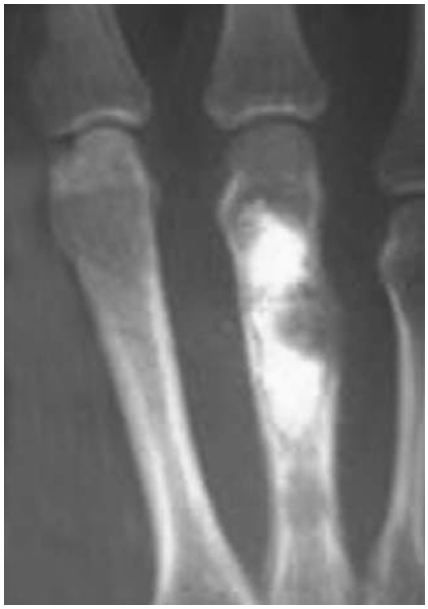


The fracture is healed after one year, PORESORB®-TCP keeps reabsorbing, and a brightening is seen very well in the filling, especially at the medial side.

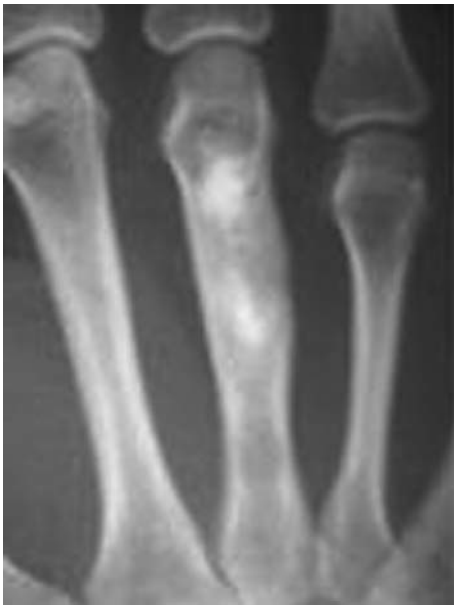
APPLICATION OF PORESORB®-TCP IN HAND SURGERY



Osteolytic defect, affecting the head and diaphysis of the third left metacarpal, was caused by benign enchondroma.



Following excochleation, the defect was filled with PORESORB®-TCP up to the diaphysis. Brightening, which is seen on the ulnar side, is caused by the presence of the returned bony window from the trepanation.



After 2 years postoperative, residuem of PORESORB®-TRC are seen as well as a well healed bone defect without any signs of recurrence.

(Assoc. Prof. K. Urban, Ph.D, Orthopaedic clinic, Faculty hospital, Hradec Králové, Charles University, Prague, Czech Republic)

PORESORB®-TCP

PORESORB®-TCP - SPECIFICATION:

Grain size (mm): 0.16 - 0.3

Cat.No: 31:2	**Cat.No:** 32:2
packaging: 1.0 g (1.0 ml)	**packaging:** 0.5 g (0.5 ml)

Grain size (mm): 0.3 - 0.6

Cat.No: 11:2	**Cat.No:** 13:2
packaging: 1.0 g (1.0 ml)	**packaging:** 0.5 g (0.5 ml)

Grain size (mm): 0.6 - 1.0

Cat.No: 21:2	**Cat.No:** 22:2
packaging: 1.0 g (1.0 ml)	**packaging:** 2.0 g (2.0ml)

Grain size (mm): 1.0 - 2.0

Cat.No: 41:2	**Cat.No:** 42:2
packaging: 1.0 g (1.2 ml)	**packaging:** 2.0 g (2.4 ml)

The manufacturing of **PORESORB®-TCP** material is subject to a quality management system which is in accordance with **ISO 9001:2000** and **ISO 13485:2003**. All **LASAK** products comply with the requirements of the EU Directive **93/42 EEC** and on the basis of the certificate of Notified Body No. 1014 of the European Union thus bear the **CE marking.**

CE 1014

LITERATURE

Internal sinus augmentation using porous resorbable calcium phosphate ceramic material; *Evaluation of osteogenic activity of PORESORB-TCP in vitro*; Nathanský Z., Strnad J., Veselý P.; , Clin. Oral impl. Res. Vol.14, 4, 2003, xxxvii • **Early interaction of biomaterials with dynamic simulated body environment;** Strnad J., Protivínský J., Strnad Z., Helebrant A., In: Proceedings of 5th Asian; Symposium on Biomedical materials, eds.: HonY. Leng and C. Y. Cheng, 9.-.12. 12. 2001, Hong-Kong, China • **Calcium Phosphate Bioceramics Characteristics-Mechanism of Osseointegration**; Hroudová Z., Povýšil C., In: Proceedings of International Congres on Dentistry; Prague, 1997 • **Internal sinus floor elevation - new dental implantology possibilities**; Nathanský, Z. Čes. Stomat. 103/51, 2003, 6:229-233, 1210-7891 • **Treatment of alveolar bone defects by porous ß-TCP and PRP**; P. Poleník, Z. Strnad, Clin. Oral impl. Res. Vol.14, 2004, xliv • **Utilization of trombocyte concentrate for regeneration of parodontal and bone tissue**; P. Poleník, Quintessenz-Parodontologie, 3, 2002, 12:15-20 • P. Poleník: **Porous ß-TCP and platelet rich plasma (PRP) in treatment of periodontal defects,** J. Int. Acad. Periodontol., 6, 2004, No. 2 • **Physical and chemical characterisation of bone regeneration materials based on TCP**; Strnadová M., Skrčená A., Nathanský Z., In: Clin. Oral. Impl. Res. Vol. 16, 4, 2005 • **Tricalciumphosphate as a bone tissue substitute (testing of biological properties in an animal model)**; Urban K., Strnad Z., Povýšil C., Šponer P., In: Acta Chir. orthop. Traum. Čech., 63,1, 1996

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