PerOssal®			
Packaging size		**Bulk volume** [3]	**Art.-No.**
1 x 6	pellets (6 mm x 6 mm)	1.5 cm^3	03-01031
2 x 6	pellets (6 mm x 6 mm)	3.0 cm^3	03-01032
1 x 50	pellets (6 mm x 6 mm)	12.5 cm^3	03-0102

PerOssal®

- The osteoconductive synthetic bone substitute
- Prolonged protection against microbial colonization if preloaded with suitable antibiotics [6, 7]
- Completely biodegradable during osteoneogenesis [5]
- No subsequent explantation necessary

References

[1] Rauschmann et al. (2005), **Nanocrystalline hydroxyapatite and calcium sulphate as biodegradable composite carrier material for local delivery of antibiotics in bone infections**, Biomaterials. 26(15):2677-2684.

[2] Englert et al. (2007), **Konduktives Knochenersatzmaterial mit variabler Antibiotikaversetzung [Conductive bone substitute material with variable antibiotic delivery]**, Unfallchirurg. 110(5):408-413.

[3] Standardized bulk volume, data on file at OSARTIS GmbH.

[4] von Stechow and Rauschmann (2009), **Effectiveness of combination use of antibiotic-loaded PerOssal® with spinal surgery in patients with spondylodiscitis**, Eur Surg Res. 43(3):298-305.

[5] Kraus und Schnettler (2008), **Gutachten bei Osteitis [Expert opinion in osteitis]**, in: Bericht über die Unfallmedizinische Tagung in Mainz am 8./9.11.2008, Deutsche Gesetzliche Unfallversicherung (Hrsg.), Heft 108, ISBN 3-88383-082-8.

[6] Fleege et al. (2012), **Systemische und lokale Antibiotikatherapie bei konservativ und operativ behandelten Spondylodiszitiden [Systemic and local antibiotic therapy of conservative and operative treatment of spondylodiscitis]**, Orthopäde. 41(9):727-735.

[7] Fleege et al. (2020), **Development and current use of local antibiotic carriers in spondylodiscitis: Pilot study on reduction of duration of systemic treatment**, Orthopäde. 49(8):714-723.

[8] Fleege et al. (2017), **Antibiotikatherapie der pyogenen Spondylodiszitis bei Erwachsenen [Antibiotic therapy of pyogenic spondylodiscitis in adults]**, Die Wirbelsäule. 01(4):265.

[9] Release kinetic data on file at OSARTIS GmbH.

[10] Visani et al. (2018), **Treatment of chronic osteomyelitis with antibiotic-loaded bone void filler systems: an experience with hydroxyapatites calcium-sulfate biomaterials**, Acta Orthop Belg. 84(1):25-29.

[11] Sakellariou et al. (2015), **Combination of Calcium Hydroxyapatite Antibiotic Carrier with Cement Spacers in Peri-Prosthetic Knee Infections**, Surg Infect. 16(6):748-54.

[12] Jiménez-Martín et al. (2008), **Use of calcium sulfate and hydroxyapatite with antibiotics in osteomyelitis of the hand: Two clinical cases. Utilidad del sulfato cálcico e hidroxiapatita con antibióticos en las osteomielitis de la mano, a propósito de 2 casos clínicos**, Trauma Fund MAPFRE 20(1):45-48.

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141-3010-06EN / 032023

OSARTIS®

PerOssal®

Resorbable Bone Substitute

PerOssal®

PerOssal® is intended for the restoration of bone defects. After thorough surgical debridement and under systemic or local antibiosis, it may be also implanted in infected or contaminated areas.

PerOssal® is a synthetic, biodegradable and osteoconductive bone substitute material for restoration and filling of bone defects. Its unique microporous structure ensures uniform uptake of liquid substances (such as antibiotics) and their controlled sustained release [1].

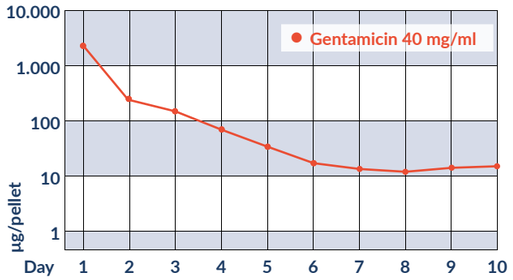
PerOssal® has a porous structure that allows the safe uptake of aqueous solutions: 0.5 ml per 6 pellets and 4 ml per 50 pellets.
These characteristics make PerOssal® the ideal carrier material.

Features

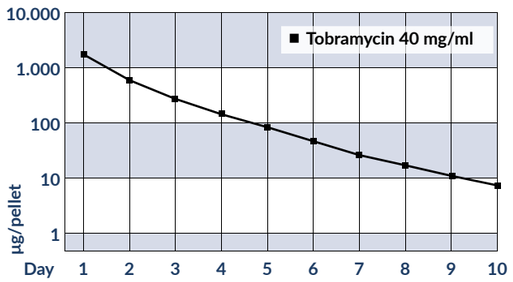
- **Nanocrystalline / porous**
  Suitable as carrier material for aqueous solutions (such as antibiotics)
- **Custom loadable**
  Targeted highly effective antibiotic protection of the bone substitute material and the surrounding tissue according to the individual antibiogram with minimum systemic side effects
- **Prolonged action**
  After drenching with antibiotics controlled long-term (10 days) protection of the bone replacement material against colonization with sensitive bacterial pathogens
- **Biodegradable**
  - Fully absorbed in dependence of the defect size, the implantation site and the quality of the surrounding bone typically within 6 months [8, 10]
  - No second procedure required for explantation

In vitro release of the tested antibiotics from PerOssal® over a period of 10 days

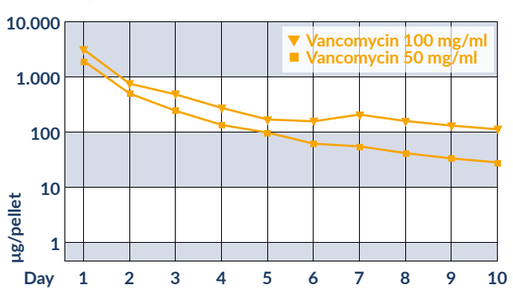
Gentamicin [2]



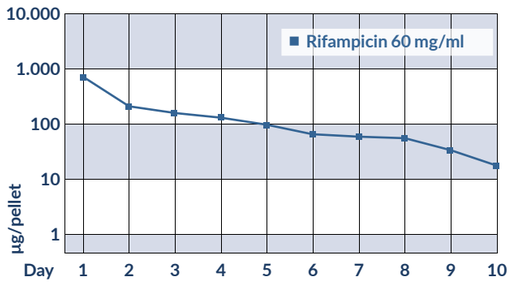
Tobramycin [9]



Vancomycin [9]



Rifampicin [9]



Dosage Recommendation* for Antibiotic Load

Antibiotics	Concentration
Gentamicin	40 mg/ml
Tobramycin	40 mg/ml
Vancomycin	100 mg/ml
Rifampicin	60 mg/ml

* recommended dosage based on in vitro results. The treating physician is responsible for the decision regarding the type and quantity of the corresponding antibiotic. The contraindications of the applied antibiotic have to be considered.

The Biological Basis

Composition:
51.5 % nanocrystalline hydroxyapatite
48.5 % calcium sulfate

Dosage Form and Packaging Sizes

PerOssal® are cylindrical pellets measuring 6 mm x 6 mm, with one spherical and one flat end. Packaging sizes of 1x6, 2x6 and 1x50 pellets are available. The pellets are primarily packed into vials, which are protected by a double peel-off packaging (inner and outer sterile packaging).

Indications

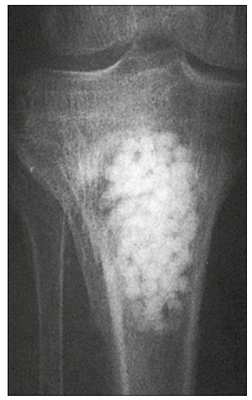
- PerOssal® is indicated for filling or reconstruction of bone defects.
- In case of infected or contaminated bone, PerOssal® is indicated after prior surgical debridement and with simultaneous systemic and/or local administration of antibiotics.
- PerOssal® can be used for augmentation of autogenous bone [4].

Possible Areas of Application

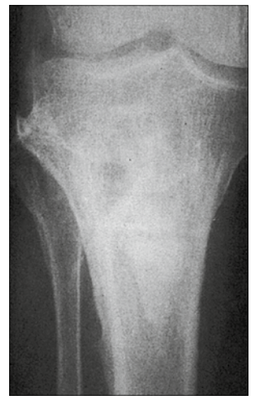
- Traumatology
- Orthopaedic surgery
- Spinal surgery
- Maxillofacial surgery

Clinical Applications

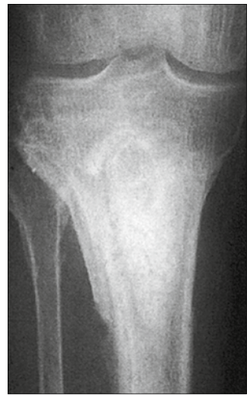
42 years old patient with fistulous osteomyelitis of the proximal tibia 28 months after plate osteosynthesis [5]



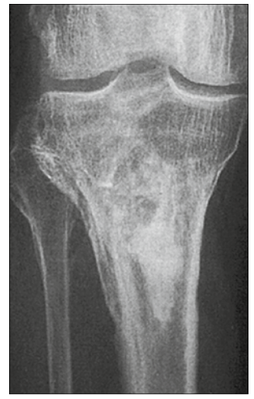
Implantation of 2 x 50 PerOssal® (25 cm³) pellets loaded with 1,000 mg vancomycin after repeated debridement (*Staphylococcus aureus*)



40% resorption of the PerOssal® pellets after the first 4 weeks



90% resorption of the PerOssal® pellets after 1 year



100% resorption of the PerOssal® pellets and completely new bone formation after 3 years; patient remained free of infection during the entire time