### 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

### Packaging size

<table>
<thead>
<tr>
<th>Size</th>
<th>Bulk volume</th>
<th>Art.-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 x 6 pellets (6 mm x 6 mm)</td>
<td>1.5 cm³</td>
<td>03-01031</td>
</tr>
<tr>
<td>2 x 6 pellets (6 mm x 6 mm)</td>
<td>3.0 cm³</td>
<td>03-01032</td>
</tr>
<tr>
<td>1 x 50 pellets (6 mm x 6 mm)</td>
<td>12.5 cm³</td>
<td>03-0102</td>
</tr>
</tbody>
</table>

### References


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


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

**PerOssal®**

**PerOssal®** is intended for the restoration of bone defects. After thorough surgical debridement and under systemic or local antibiotics, 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 [2, 3]
  - No second procedure required for explantation

**Dosage Recommendation** for Antibiotic Load

<table>
<thead>
<tr>
<th>Antibiotics</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>40 mg/ml</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>40 mg/ml</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>50 mg/ml</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>60 mg/ml</td>
</tr>
</tbody>
</table>

*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.

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

**Gentamicin** [2] / **Tobramycin** [9]

- **Vancomycin** [3]

- **Rifampicin** [4]

**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).

**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*)

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