Filling bone defects – protecting healing bones
Infections present one of the greatest challenges in orthopaedics and traumatology. With a risk of infection of up to 30%, prevention of infection is becoming increasingly important.

As a long-standing expert in bone cement and biomaterials, Heraeus has extensive experience with the application of local antibiotics in arthroplasty and in musculoskeletal infections, with a view to preventing infection. Based on this expertise, Heraeus develops innovative products for infection management in orthopaedics and in traumatology.

HERAFILL®, which contains antibiotics, is a unique bone void filling material for the complex requirements of dead space management. Thanks to the addition of the proven broad-spectrum antibiotic Gentamicin, HERAFILL® enables efficient infection management for a wide range of indications – in orthopaedics/traumatology, and for septic and aseptic scenarios.
HERAFILL® BEADS G
Resorbable bone void filling material with the benefit of infection prevention

CALCIUM SULPHATE
The primary component of HERAFILL® beads G is a substance proven in orthopaedics and traumatology with effective resorption behaviour.

CALCIUM CARBONATE
Calcium carbonate has a neutralising effect on the pH level, increases the duration of resorption and reduces wound secretion.

TRIGLYCERIDE
Triglyceride provides for optimum bonding of the HERAFILL® components.

GENTAMICIN
The broad-spectrum antibiotic Gentamicin, prevents bacterial colonisation by bacteria sensitive to Gentamicin. One bead contains 2.5 mg of the antibiotic.

Composition of HERAFILL™ beads G

GENTAMICIN CONCENTRATION FOLLOWING IMPLANTATION OF HERAFILL® BEADS G

Local antibiotic prevention using HERAFILL® beads G results in a high local concentration of Gentamicin, as well as a low systemic antibiotic load.
NUMEROUS INDICATIONS. ONE SOLUTION.
The HERAFILL® triple effect for dead space management

RESORPTION
Calcium carbonate has a neutralising effect on the pH level, increases the duration of resorption and reduces wound secretion. Depending on the blood supply, the location of implantation, and the patient status, HERAFILL® beads G are biodegraded completely in the bone within a few months. The healing of the bone is supported without impairing bone growth.

COMBINATION
HERAFILL® beads G can be combined as a volume expander with osteoinductive and stabilising materials (e.g. bone chips, spongiosa, or hydroxyapatite).

PROTECTION
Prevention of infection through a high local level of Gentamicin: Gentamicin is a proven antibiotic in orthopaedics and traumatology with a broad spectrum of action against numerous clinically-relevant pathogens.

<table>
<thead>
<tr>
<th>Septic indication</th>
<th>Aseptic indication</th>
</tr>
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<tbody>
<tr>
<td>Goal</td>
<td>Prevention of infection with a view to minimising the risk of infection.</td>
</tr>
<tr>
<td>Examples</td>
<td>Filling a defect following a fracture or removal of osteosynthesis material.</td>
</tr>
<tr>
<td>Dead space management in the case of osteitis and osteomyelitis, infected pseudarthrosis/non-union</td>
<td>Filling a defect following a non-malignant tumour.</td>
</tr>
</tbody>
</table>

HERAFILL® beads G can be used for a wide range of indications: Orthopaedics/traumatology, septic and aseptic scenarios.
CASE REPORTS: SEPTIC INDICATION

Osteitis of the femur
Infected non-union following a fracture of the tibia

Chronic osteomyelitis of the femur
Chronische Osteomyelitis des Femurs

Chronic osteomyelitis of the humerus*
Infected non-union of the distal radius*

Osteoarthritis of the knee following pyogenic infection of the femur

Infected non-union following a fracture of the tibia
Chronic osteitis of the tibia*

Chronic osteomyelitis of the metatarsal bone

* Case report on the following pages
Additional case reports available on request
MANAGEMENT OF CHRONIC OSTEOMYELITIS OF THE HUMERUS WITH HERAFILL® BEADS G

Cierny-Mader 3A chronic haematogenous osteomyelitis

Mr Martin McNally, Nuffield Orthopaedic Centre, Oxford University Hospitals, Headington, Oxford, OX3 7HE, UK
E-Mail: martin.mcnally@ouh.nhs.uk

| Patient | ■ Female, Age: 39 years, Weight: 64 kg |
| History | ■ At age 13 years, while living in Ghana, developed pain and discharge from the lower part of her left humerus, diagnosed as acute osteomyelitis  
■ Antibiotics for 2–3 weeks  
■ Intermittent swelling and pain in the next few years; treatment with several courses of antibiotics, but no surgery |
| Indication | ■ Severe pain in left arm present for 3–4 months  
■ Episodes of high temperature and nausea. Recent weight loss and lethargy |
| Medical history | ■ Preoperative x-ray, CT and MRI confirmed extensive Cierny & Mader type 3A osteomyelitis  
■ Cortical thickening, medullary lysis and sequestrum formation  
■ Pre-op blood tests: Hb 10.6 g/dl; WCC 12.1; CRP 125 mg/l  
■ No microbiological diagnosis was available before surgery |
| Surgery | ■ The lower humerus was opened and a large amount of pus and necrotic tissue was removed. Deep samples were taken for microbiology and histology. The canal was reamed and the defect filled with 40 HERAFILL® beads G. The wound was closed directly.  
■ IV Vancomycin and Meropenem given after sampling  
■ Volume: 18 cm³  
■ Number of beads: 40 |
### Immediate post-op
- IV Flucloxacillin 2 g, 4x per day for 7 days
- Laboratory examination revealed profuse growth of staphylococcus aureus
- Followed by Clindamycin and Rifampicin orally for 3 months
- The wound healed fully within a few days of the operation with no wound leakage

### Outcome
- Blood tests 4 weeks post-op: Hb 10.4 g/dl, WCC 9.3, CRP < 6 mg/l, ESR 12 mm/hr
- At 8 weeks: back to full use
- At 3 months: pain free with excellent shoulder movement and good elbow movement; dissolution of the beads with no signs of recurrent infection and no fracture
- At 1 year: no evidence of recurrence. Her x-ray showed good remodelling of the humerus

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*Continued bone remodelling with no sign of infection*
**APPLICATION OF HERAFILL® BEADS G IN THE TREATMENT OF AN INFECTED NON-UNION OF THE DISTAL RADIUS**

*Infected non-union following open reduction and internal fixation (ORIF)*

Dr. Alexander Horst, St. Josef Hospital Essen-Kupferdreh, Orthopaedics and Trauma Surgery, Heidbergweg 22–24, 45257 Essen-Kupferdreh, Germany, email: A.Horst@kkrh.de

<table>
<thead>
<tr>
<th>Patient</th>
<th>Female, 87 years</th>
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</table>
| History | October 2012: Dislocated fracture of the left distal forearm following a fall, with an open fracture of the radius close to the joint  
October 2012: ORIF with a titanium locking plate; Surgical technique: palmar approach; Acceptable reduction result, despite a shortening of the radius |
| Indication | Delayed healing of the fracture two months following open reduction and internal fixation |
| Medical history | Clinical indications of a soft tissue infection  
Radiological indications of secondary reduction loss with loosening of the implant  
No serious comorbidities or risk factors  
Preoperative evidence of staphylococcus aureus (sensitive to Gentamicin) |
| Surgery | Removal of the plate and of the distal screws that had loosened completely  
In situ, a bone defect of approx. 20 x 10 mm was evident, that was filled with infected soft tissue  
Radical debridement of the infected tissue  
Filling the defect using 7 HERAFILL® beads G  
Fixation was performed using a mini fixation device with slight elongation and bridging of the joint |
<table>
<thead>
<tr>
<th>Immediately after surgery</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ No clinical indications of infection</td>
<td></td>
</tr>
<tr>
<td>■ WBC and CRP fall significantly, approaching the normal range</td>
<td></td>
</tr>
<tr>
<td>■ No change in the position of the fracture fragments and of the HERAFILL® beads G</td>
<td></td>
</tr>
<tr>
<td>■ Wound healing without irritation</td>
<td></td>
</tr>
<tr>
<td>■ Oral administration of Clindamycin</td>
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</tbody>
</table>

- **Immediately after surgery**

- **3 weeks after surgery**

- **7 months after surgery**

- **14 months after surgery**

- **Outcome**

- **After 3 weeks:** No clinical indications of infection, only slight pain, almost full mobility of the finger. Radiological indications of consolidation, as well as of resorption of the HERAFILL® beads G, which have decreased in volume and exhibit a cloudy appearance. Removal of the external fixation device is carried out.

- **After 7 months:** Clinically discrete swelling of the soft tissue apparent, no indication of infection. Sufficient function with extension and flexion of approx. 20°. Fracture is fully healed and the defects restored. HERAFILL® beads G have been completely resorbed.

- **After 14 months:** Full restoration of the bone defects and healing of the fracture without any change of position. No indication of post-traumatic arthritis of the carpal joint. In comparison to the right wrist, mobility of the left wrist is slightly restricted in extension and flexion.

*The patient is clinically free from infection with sufficient function in her left arm*
# APPLICATION OF HERAFILL® BEADS G IN THE TREATMENT OF CHRONIC OSTEITIS OF THE TIBIA

**Recurring chronic osteitis of the right tibia**

Dr. G. Walter, BG Trauma Clinic, Friedberger Landstrasse 430, 60389 Frankfurt am Main, Germany
Correspondence: Christian Brüning, email: christian.bruening@bgu-frankfurt.de

<table>
<thead>
<tr>
<th>Patient</th>
<th>Male, 24 years; Weight: 84 kg; Height: 178 cm</th>
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| History | Polytrauma patient; Fracture of the distal tibia, compartment syndrome and injury to the tibial nerve  
- The wound became infected, fistula formation occurred with secretion from the scar. In addition, osteolysis of the pilon fracture was also apparent  
- As part of a first step, a sequestrectomy was carried out with implantation of a PMMA chain |
| Indication | Chronic osteitis with fistulas |
| Medical history | See history  
- No microbiological diagnosis available prior to surgery |
| Surgery | Explantation of the PMMA chain followed by radical debridement, as well as sample collection for microbiological purposes  
- Systemic intraoperative administration of Sultamicillin following sample collection  
- Filling the defect using autologous spongiosa from the iliac crest in combination with HERAFILL® beads G  
- Defect volume: 15 cm³  
- Implantation of 67 HERAFILL® beads G |
Immediately after surgery

- Weight-bearing pain
- Wound healing well
- Evidence of pathogen indicates development of *Staphylococcus aureus* (sensitive to Gentamicin)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>3 months after surgery</th>
<th>9 months after surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 4 weeks: Patient is pain-free without the use of pain relief, continued oral administration of antibiotics, no irritation, swelling or reddening of the wound. Full weight bearing on the part of the patient</td>
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<tr>
<td>After 3 months: The patient is doing well, HERAFILL® beads G are still visible on the x-ray, while the defect can already be seen to have reduced considerably in size</td>
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<tr>
<td>After 6 months: The patient continues to do well with full weight bearing</td>
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<tr>
<td>After 12 months: The patient is doing well, full resorption of the beads is apparent on the x-ray, at the same time the size of the osteolytic defect has been further reduced, but it still remains visible</td>
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</table>

It was not possible to achieve complete bone consolidation within a year, however, the patient remains clinically free from infection. It was possible to achieve an effective basis for further bone consolidation.
"Did you know that local antibiotics play an important part in the infection management of bone defects?"

THE KEY:
A high local antibiotic concentration enables both effective prevention of infection and a low systemic load.

Effective management of infection in orthopaedics and traumatology – with HERAFILL® from Heraeus

<table>
<thead>
<tr>
<th>HERAFILL®</th>
<th>Description</th>
<th>Contents</th>
<th>REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>HERAFILL® beads G</td>
<td>Resorbable bone substitute/bone void filling material with Gentamicin</td>
<td>1 x 20 beads (≤ 5 ml bulk volume)  1 x 40 beads (≤ 10 ml bulk volume)</td>
<td>66039634  66039635</td>
</tr>
</tbody>
</table>

RECOMMENDED DOSAGE:
Maximum amount of HERAFILL® beads G = body weight in kg x 1 bead

Simply order from Heraeus.

www.heraeus-medical.com