Refobacin® Revision

Antibiotic-loaded bone cement containing both gentamicin and clindamycin developed specifically for one- and two-stage revision surgeries, infections and high-risk patients.
Refobacin® Revision

Refobacin Revision is a high viscosity, x-ray positive bone cement. It is a bone cement from Biomet, containing a combination of the two antibiotics gentamicin and clindamycin. This antibiotic combination has the advantage of offering both a high local antibiotic concentration and a broad antibacterial spectrum. 40 gram Refobacin Revision contains 1 gram gentamicin and 1 gram clindamycin. The cement increases the available options for preventing infections and re-infections in total joint replacements.

Refobacin Revision is developed from Refobacin Bone Cement R specifically for one- and two-stage revision surgeries, infections and high-risk patients. Its combination of gentamicin and clindamycin is known to have an antibacterial effect on more than 90% of the bacteria common to infected arthroplasty cases. 3

As all Biomet cements, Refobacin Revision contains chlorophyll, which gives the cement its characteristic green colour, for easy distinction from bone and body tissue during surgery.

In both the Norwegian Arthroplasty Register and in the Swedish Hip Arthroplasty Register the use of high viscosity cements with gentamicin has been shown to result in the lowest incidence of revision.4,5 The reduced revision incidence in turn reduces the associated costs.5

1) Swedish Hip Arthroplasty Register, 2005
Control of quality and mechanical properties

HIGH QUALITY STANDARD
As the responsible manufacturer of Refobacin Revision, Biomet maintains a high quality standard. During production all raw materials have to fulfill demanding specific criteria. Refobacin Revision, as well as all other cements from Biomet undergo rigorous quality control under ISO 13485 and pharmaceutical standards, to guarantee a consistent high quality.

EXCELLENT MECHANICAL PROPERTIES
Bone cement is subjected to high mechanical stress. The mechanical properties of bone cement must therefore be tested for compressive strength, bending strength and Young’s modulus according to ISO 5833. Refobacin Revision exceeds the international standards established for strength (see illustrations).

“The cement increases the available options for preventing infections and re-infections in total joint replacements”

7) Internal studies, Biomet Deutschland GmbH, Dieburg, Germany
Two antibiotics for increased efficiency

Once settled, germs are less sensitive to antibiotics, rendering treatment with antibiotics ineffective. A solution to this problem is preventing the colonizing of germs. By using an antibiotic-loaded bone cement, high local concentrations of antibiotics can be administered, preventing exogenous and endogenous germs from colonizing. The protracted release of the antibiotics protects the implant for an extended period of time. While local antibiotic concentration is high in order to protect the implant, antibiotic levels in the serum and urine remain low, precluding side effects.

ANTIBIOTICS IN BONE CEMENT
Antibiotics added to bone cement must have the following characteristics:⁸ ⁹

- Broad coverage of the targeted bacterial spectrum
- Excellent release from bone cement
- Good thermal stability
- Resistance to sterilization

GENTAMICIN AND CLINDAMYCIN—OPTIMAL ANTIBIOTICS FOR BONE CEMENT
Gentamicin is bactericidal on proliferating and resisting pathogens and has proven to be the antibiotic of choice for bone cement. With its broad therapeutic spectrum, gentamicin covers a wide variety of gram-positive and gram-negative bacteria.¹⁰ The gentamicin has been specially treated by Merck KGaA according to a process proprietary to Biomet.

Clindamycin has a predominantly bacteriostatic effect on gram-positive bacteria such as staphylococci and streptococci as well as on gram-positive and gram-negative anaerobes. The combination of clindamycin and gentamicin is the most appropriate weapon in both one- and two-stage revisions because most pathogens causing periprosthetic infections have a susceptibility pattern covered by these agents.¹⁰

HIGH LOCAL ANTIBIOTIC CONCENTRATION
Antibiotic-loaded cements such as Refobacin Revision

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¹⁰ Gehrke T, von Förster G, Frommelt L (2001) Pharmacokinetic study of a Gentamicin/Clindamycin Bone Cement Used in One-Stage Revision Arthroplasty. In: Bone Cements and Cementing Technique; Walenkamp, GHIM; Murray, DW (eds); Springer Verlag Berlin Heidelberg; pp 177-134
provide effective concentrations of gentamicin and clindamycin in the tissue surrounding the implant. Additional clinical advantages of gentamicin- and clindamycin-loaded cements include low systematic and urinary antibiotic concentrations and a consequent lack of ototoxic and nephrotoxic complications.

**GENTAMICIN-LOADED CEMENTS WITH PROVEN CLINICAL RESULTS**

A considerable number of published case studies have confirmed the successful use of antibiotic-loaded cements.\(^\text{11, 12}\) Gentamicin-loaded cements in particular have shown good clinical results in both the Swedish Hip Arthroplasty Register and the Norwegian Arthroplasty Register.

**LONG-LASTING LOCAL ANTIBIOTIC RELEASE**

Both gentamicin- and clindamycin-loaded cements have a significantly higher in vitro release than most other antibiotics.\(^\text{13}\) These two antibiotics show similar elution properties with regard to both concentration and duration when mixed with bone cement in the same concentrations.\(^\text{10}\)

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One- and two-stage revisions

ONE-STAGE REVISION
Although the results of primary total hip and knee arthroplasties generally are excellent, some failures do occur over time. During one-stage revision surgery, the implant, the former cement mantle and all foreign material are removed. After a thorough lavage, and in some cases bone impaction, the prosthesis components are fixed with an antibiotic-loaded cement.

TWO-STAGE REVISION
In a two-stage revision, a patient matched temporary spacer made of antibiotic-loaded cement such as Refobacin Revision may be used. This temporary cement spacer prevents bone-on-bone contact and contraction of soft tissue and also stabilizes the infected joint. The non weight-bearing spacer remains in place until the infection has been successfully treated, normally 6-8 weeks. It is then removed and replaced with a conventional joint prosthesis.

PATIENT MATCHED CEMENT
Biomet’s standard range of bone cement covers most cases when cemented arthroplasty is necessary. Sometimes however, these cements are not adequate. In such cases, Biomet can offer a patient matched bone cement manufactured according to the European Medical Device Directive.* Patient matched bone cement is made specially for a certain patient and the main indication is MRSA.

* Patient matched bone cements are produced upon request from the surgeon, using the patients antibiogram.

Easy handling
For mixing and delivery of Refobacin Revision it is recommended to use a closed vacuum mixing system, such as Biomet’s Optivac®.

This ensures a reproducible, homogeneous bone cement of high quality. Handling properties are very dependent on the temperature of the bone cement and operating room. Higher temperature results in shorter working phase and faster setting time. If the cement is pre-chilled both the working phase and the setting time are prolonged.

Application of non-prechilled Refobacin Revision mixed under vacuum
I: mixing phase     III: application phase
II: waiting phase   IV: final hardening phase

Handling spacer molds

Biomet offers various sizes of spacer molds for the knee and hip. These molds can be used to produce temporary cement spacers for infected joints. For these applications an appropriate antibiotic-loaded cement should be used.

The joint spacer molds are sterile disposables made of medical grade silicone. They can be filled with bone cement by injection with a cement delivery gun. After the cement has cured, the temporary spacer is removed from the mold and the joint spacer is now ready for use.

**Hip**

1. Fill the stem of the mold first.
2. Continue the filling of cement into the head.
3. Once the cement is cured, press thumbs into the depression on the bottom of the mold foot and peel the mold away from the hip spacer. Trim the hip spacer if necessary.
4. Ready spacer and its mold.

**Knee**

1. Fill the tibial mold by injecting cement into its open top.
2. Fill the femoral mold by injecting in the delivery port.
3. When cured, remove the spacer from the mold.
4. Ready spacers and their molds.

*Detailed instructions on how to use Biomet’s spacer molds are found in the instructions for use included in the package.*
Refobacin Revision with gentamicin and clindamycin

3011630001
1 x 40
1 sachet of 42.9 g powder
1 ampoule of 20 ml liquid

### Hip Cement Spacer Molds
Collarless bi-metric style stem with an endo style head

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### Knee Cement Spacer Molds
Cruciate sacrificing universal AGC style components

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• Prevents bone-on-bone contact and soft tissue contraction
• Stabilizes infected joints
• Various sizes for both hip and knee
• Aids joint mobility and function recovery
• Accommodates protracted antibiotic release
Refobacin Revision is a bone cement from Biomet, containing a combination of the two antibiotics gentamicin and clindamycin, tailor-made for revision surgeries. Refobacin Revision is however only a small part of Biomet’s complete bone cement range, which also includes:

**ANTIBIOTIC LOADED CEMENTS**
- Refobacin Bone Cement R
- Refobacin Plus Bone Cement

**PLAIN CEMENTS**
- Biomet Bone Cement R
- Biomet Plus Bone Cement

**SPECIALITY CEMENTS**
- Biomet Bone Cement V
- Biomet Bone Cement LV

Endorsed by Dr. Thorsten Gehrke, Endo-klinik, Hamburg