

Patient Information Leaflet for Bone Cement (e.g. Hip or Knee)

This leaflet has information about your bone cement. It does not contain all the information and if you have any questions, talk to your healthcare team. All medical devices have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.

The name and number of your bone cement can be found on your implant card. If a healthcare professional asks about your bone cement, please show them your implant card.

Device Description

The device used in your operation is intended to secure the prosthesis to the bone. The bone cement sets hard and acts to connect the joint implant (e.g. Knee or Hip) to the bone. Bone cement with an antibiotic (Gentamicin Sulphate) can be used when there is a risk of infection by bacteria which can be treated using Gentamicin Sulphate. The bone cement is implanted within your body, where appropriate, any mixing system used is not and is only used to mix and apply the bone cement during the operation.

Your doctor will choose the bone cement to meet your medical needs.

Device Material

Component	Material
Bone Cement Powder	Polymethyl Methacrylate, Methyl Methacrylate / Styrene Copolymer, Methyl Methacrylate / Methyl Acrylate Copolymer, Benzoyl Peroxide, Barium Sulphate, Zirconium Dioxide, with or without Gentamicin Sulphate
Bone Cement Liquid	Methyl Methacrylate, N,N-Dimethyl- <i>p</i> -toluidine, Hydroquinone

Information for Safe Use

As part of your operation, you should have received a set of instructions regarding exercises, therapies and any limitations on your activities. It is very important you follow your doctor's instructions about how to recover and restart activities. Make sure you attend all appointments. Healing takes time and your doctor will provide information on what to expect. Not following your doctor's advice may result in complications and the need for an additional operation. If you are asked to go for an MRI scan (process for imaging body parts) please show your implant card to the doctor and MRI technician. Your bone cement is MRI safe and can also be used under CT scan or x-ray.

Possible Side Effects / Risks

Information about the possible side effects of your operation are available from your doctor. All operations have risks. The risk of a serious complication is low. There is a risk that the joint replacement can wear out earlier than expected or go wrong in some way. Please talk to your doctor if you have concerns about changes in your joint replacement.

Possible risks may include:

- Pain, dislocation of the joint, stiffness or uneven leg length
- Implant loosening change in position or wear
- Bone loss, fracture or perforation
- Infection or delayed wound healing
- Allergic response or adverse biological response
- Squeaking or noise during use
- Implant breaks, bends, cracks or separates
- Permanent or short-term nerve damage or tissue damage
- Heart attack, blood clots, or stroke
- Elevated blood GGTP (Liver Enzyme) up to 10 days post operation

Expected Implant Lifetime and Follow Up

The bone cement is intended to remain in your body.

Having a joint replaced is a major operation. Most people have a good result. Your results may vary. Factors such as your anatomy (your size and shape), medical condition, lifestyle (e.g. weight and activity level) and operation affect the outcome.

Some countries or regions have joint replacement registries which monitor the performance of joint implants. This registry data was analysed and shows that for a person's first total joint operation generally 95% (95 out of 100) last more than 10 years. This means that at 10 years about 5% (5 out of 100) of patients may have had additional surgery to remove part(s). For a hemi hip replacement the risk of additional operations increases slightly. Revision joint replacement has a higher risk of an additional operation. Your implant lifetime may be longer or shorter than the average. It is not possible to predict if you will have complications which may require additional operations. The lifetime for your joint replacement is dependent on your specific medical needs. Your surgeon has access to data published for your implant and will be able to provide more information based on your specific needs. Make sure you attend all your medical appointments.

The bone cement used in your operation may contain an antibiotic (Gentamicin Sulphate). In the day(s) following your surgery the antibiotic is released from the cement and is intended to reduce the risk of infection.

Reporting Adverse Effects

If you wish to report any adverse effects you believe are a result of your bone cement, please speak with your medical team or report the information to Johnson & Johnson Medical Product Safety Department at productsafetyjjmanz@its.jnj.com and the Therapeutic Goods Administration at <https://www.tga.gov.au>

For access to this leaflet, please visit: <https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets>

Sponsor

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List of Products:

SmartSet Bone Cement

DePuy CMW Bone Cement