Patient Information Leaflet – Australia
Bone Cement

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Dear Patients,

Zimmer Biomet is committed to protecting the health and safety of all Zimmer Biomet patients. To ensure you are provided with sufficient information about your implant, along with this leaflet, you will also have the Patient Implant Card that holds important information about your implant. If you need medical assistance, show your card to the attending doctor at your health facility.

The name and reference / model number of your implant can be found on your implant card. Additional information specific to your implant may be found by following the directions found at ifp.zimmerbiomet.com.

If you have any questions about your implanted medical device(s), including your instructions on recovery, follow-up, or activity restrictions, or you experience any unusual or increased pain, swelling, or redness around your surgery site, please contact your doctor.

If there is anything in this leaflet that you are not sure about, or anything you do not understand, please contact your doctor, who will then be able to provide you with any information required.

What are these implants?

Bone cement is intended to secure your implant to the bone during joint replacement surgeries. It is suitable for patients (as determined by your doctors) for a joint replacement.

What does my implant do?

Bone cement is suitable for use in patients who require a hip or knee replacement surgery during which their hip or knee joint is replaced by an artificial implant.

What is my implant made of?

If you have any questions about your bone cement, ask your doctor.

Bone cement is made of materials that have been used in bone cements for many years. It meets international safety and design standards.

Bone cement is produced by mixing two components, Cement Powder and Liquid (Monomer), together. The compositions of these two components are described below.

Composition

The Cement Powder contains:

poly (methyl acrylate, methyl methacrylate) - 85 %

zirconium dioxide - 12 %

benzoyl peroxide - 1 %

gentamicin sulfate - 2 %

The liquid monomer contains:

methyl methacrylate 98 %

N,N-dimethyl-p-toluidine (DmpT) 2 %

In addition: hydroquinone, chlorophyll VIII

The content of active gentamicin below:

Size	Active gentamicin
20	0.28 g
40	0.55 g
60	0.83 g

How often will I need to visit the doctor?

Your doctor will decide. This will depend on your individual situation, medical history, and other medical conditions you have.

How long will my implant last and how should I care for my implant including follow-up?

Your implant is not the same as normal healthy bone and cartilage. Your implant has limitations, which you should keep in mind. These limitations can impact your lifestyle. An implant put under too much stress can break, dislocate, wear out or be damaged.

Reasons for implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions

If the implant is used under normal conditions and if you follow the detailed instructions from your doctor, the implant can last for a certain lifetime during which it functions as intended in a human body. However, all implants may need replacement at some point. If you experience any unusual or increasing pain, redness or swelling, or if you develop a limp, contact your doctor.

Many factors could have an effect on how long your implant lasts. An implant might last longer or (considerably) shorter due to surgical and / or patient specific circumstances and characteristics.

Some factors are controlled by your doctor, such as:

- Selecting the proper implant for you
- The technique used during the surgery
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- How active you are
- Your lifestyle choices
- Your weight
- Following the instructions of your doctor after surgery

But other factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have as well as its stage
- The condition of your bones
- The condition of your muscles and / or tissues

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- Infections
- Other surgeries

These factors can also change as you get older.

If you need an MRI scan, discuss the scan with your doctor, inform the health facility staff that you have an implant and show them your implant card.

You implant may also cause an alarm at a security scanner. Show your implant card to the security staff.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general. There are complications such as pain, blood clots, and nerve injuries. The implant can also break. You may also not heal properly after the surgery. Other issues in your bones and tissues can also occur.

In addition, there may be complications that can shorten the life of the implant and lead to early replacement. These may include, but are not limited to:

- Bone / tissue loss or damage
- Decreased joint movement, stiffness or uneven leg length
- Dislocation, implant loosening or wear
- Infection
- Implant breaks, bends, cracks or separates
- Sensitivity or allergic response to the materials in the implant
- Swelling

What should I do if I need advice or have a problem?

Always follow the information provided by your doctor and other medical staff. This information will include:

- Advice for best recovery after surgery
- Warnings of the general risks related to your surgery and your implant
- Possible complications (side effects)

Contact your doctor if you have questions about how your implant functions.

If you experience any unusual or increasing pain, redness or swelling, or if you develop a limp, contact your doctor.

Please report any serious incidents related to your implant by informing the TGA sponsor (Zimmer Biomet Pty Ltd) and TGA (Therapeutic Goods Administration).

Sponsor:
Zimmer Biomet Pty Ltd
Level 4, 12 Narabang Way, Belrose, NSW, 2085
Email: PER.ANZ@Zimmerbiomet.com
Phone: 02 9483 5400
Website: zimmerbiomet.com

Therapeutic Goods Administration
PO Box 100
Woden, ACT 2606, Australia
Telephone: 1800 020 653
Fax: 02 6203 1605
Website: https://www.tga.gov.au/
Users Medical Device Incident Report Form available at:

https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=-301716808

Manufacturer Details:

Zimmer Biomet Pty Ltd is the distributor of various medical devices in Australia.

To find manufacturer details of your implant, please refer to the patient implant card supplied by your Surgeon/Hospital and locate the manufacturer symbol (examples below).

Zimmer Inc.
1800 W Center Street
WARSAW, Indiana 46580
USA

Biomet Trauma
56 East Bell Drive PO Box 587
Warsaw IN 46581
USA

List of Products

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Disclaimer

Zimmer Biomet does not practice medicine. The treating surgeon is responsible for determining the appropriate treatment, techniques, and products for each individual patient.

Results are not necessarily typical, indicative, or representative of all recipient patients. Results will vary due to health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Only a medical professional can determine the treatment appropriate for your specific condition. Appropriate post-operative activities and restrictions will differ from patient to patient. Talk to your surgeon and whether this surgery is right for you and the risks of the procedure, including the risk of infection, loosening or failure.

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