

Patient Information Leaflet for Knee Joint Replacement

This leaflet has information about your implant. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants 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 knee replacement implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Implant Description

Your knee implant is intended to replace your natural knee joint. Like your natural knee joint, the implant works with the tissue and bone around your knee.

- Total knee replacement: this is where the ends of the shin bone and thigh bone are replaced. Part of your kneecap may also be replaced
- Revision knee replacement: this is where part(s) of your knee replacement is changed during an additional operation

Your doctor will choose the implants to meet your medical needs.

Implant Material

The materials within your medical device may be constructed from the following: Titanium Alloy, Hydroxyapatite, Cobalt Chrome Alloy, Ultra-High Molecular Weight Polyethylene, Stainless Steel Alloy, Alumina Based Ceramic, Polyether ether Ketone (PEEK).

If your implant contains Cobalt Chrome Alloy material, your implant contains cobalt. Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

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 that 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 additional operations.

Images of your implant are often needed after your operation. X-rays and/or CT scans of your implant will not damage your implant or increase your risk of complications. If you are asked to go for an MRI scan please show your implant card to the doctor and MRI technician. The MRI scan may interact with your implant and may cause complications if your technician is unaware of your implant. This will allow them to manage your MRI scan safely.

Possible Side Effects / Risks

Information about the 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 you may require additional operations or treatments for a variety of reasons. Please talk to your doctor if you have concerns about changes in or near your knee joint or leg.

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.
- Implant breaks, bends, cracks or separates.
- Permanent or short-term nerve damage or tissue damage.
- Heart attack, blood clots, or stroke

These risks may require additional operations or treatments. This list does not include all risks. Your doctor can further explain the risks of your operation.

Expected Implant Lifetime and Follow Up

Your implant is designed to remain in your body.

Having a knee joint replaced is a major operation. Most people have a good result, but results vary and you may have complications. Factors such as your anatomy (your size and shape), medical condition, lifestyle (for example, weight and activity level) and surgery affect the outcome.

Implant lifetime is the time from implantation of your knee replacement to when part (or all) of your knee replacement is removed from your body. Some countries or regions have knee replacement registries which monitor the performance of knee implants. This registry data was analysed and shows that for a person's first total knee 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 operations to remove part(s). For revision knee replacement generally 80% last more than 10 years. Your implant meets this general implant lifetime. Your implant lifetime may be longer or shorter than the average. It is not possible to predict if you will have complications that may require additional operations. The lifetime for your knee replacement is dependent on your specific medical history and the risk of revision for an individual patient will depend on patient specific factors such as their anatomy, medical condition and lifestyle (e.g. weight and activity level), the surgical procedure and process. 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.

Reporting Adverse Effects

If you wish to report any adverse effects you believe are a result of your knee replacement, please speak with your medical team or report the information to Johnson & Johnson Medical Product Safety Department at productsafetyjmanz@its.jnj.com or 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

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