

Patient Information Leaflet for Hip Joint Replacement

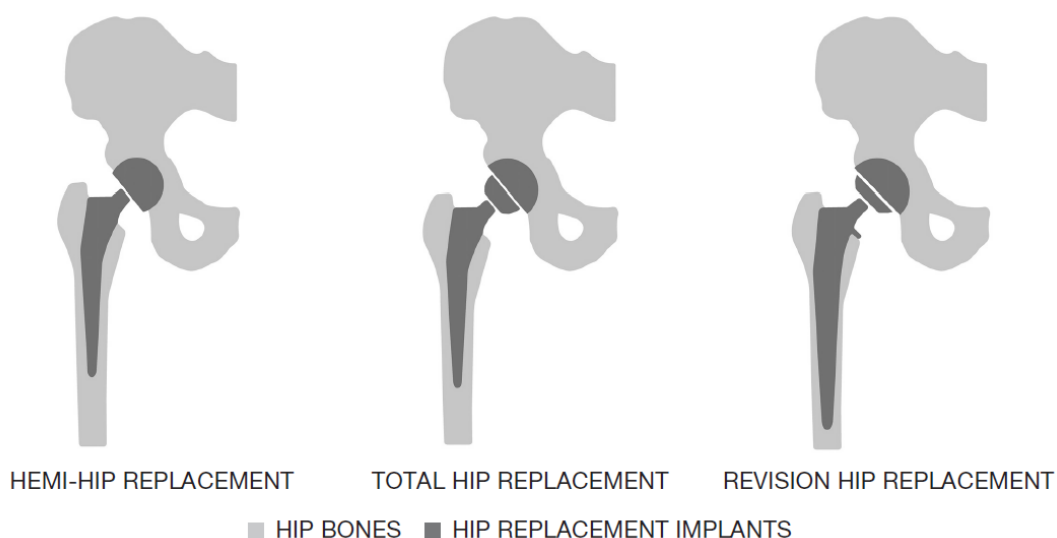
This leaflet has information about your implant. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully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

The name and number of your hip 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 hip implant is intended to replace your natural hip joint.

- Total hip replacement: this is where the ends of bones in the hip joint are replaced
- Hemi hip replacement: this is where only the end of long bone of the hip joint is replaced
- Revision hip replacement: this is where part(s) of your hip replacement is changed during an additional operation



Your doctor will choose the implant(s) to meet your medical needs. Like your natural hip joint, the implant works with the tissue and bones around your hip.

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 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. Your implant will not increase risk if you have an x-ray (including CT scans). If you are asked to go for an MRI scan, please show your implant card to the doctor and MRI technician. The 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 the hip 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 or near your hip 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
- 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

These risks may require additional operations or treatments or may affect the other joints or parts of your body. Another operation may not be possible in all patients. This list does not include all risks. Please talk to your doctor if you have concerns.

Expected Implant Lifetime and Follow Up

Your implant is designed to remain in your body.

Having a hip 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 (size and shape), medical condition, lifestyle (e.g. weight and activity level) and surgery affect the outcome.

Implant lifetime is the time from implantation of your hip replacement to when part (or all) of your hip replacement is removed from your body. Some countries or regions have hip replacement registries which monitor the performance of hip implants. The results vary and patients' implant lifetimes may be longer or shorter than the averages reported in the registries. This data was analysed and shows that for a person's first total hip 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 surgery increases slightly. Revision hip replacement has the highest risk. It is not possible to predict if you will have complications which may require additional operations. The lifetime of your hip 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.

Reporting Adverse Effects

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

Actis DuoFix
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