# Patient Information Leaflet for Shoulder 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 shoulder 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 shoulder implant replaces your natural shoulder joint. Shoulder replacement surgery involves replacing portions of the shoulder joint with artificial parts (implants). The head of the humerus (ball on the humerus, or long bone of the arm) and/or the glenoid (socket on the scapula, or the shoulder blade) may be replaced. A shoulder replacement is used to help reduce pain and/or stiffness.

A total shoulder replacement is where the whole shoulder joint is replaced. A hemi-shoulder replacement is where only the head of the humerus is replaced.

Your doctor will choose the appropriate implants to meet your needs. As with your natural joint, the joint replacement works with the tendons, ligaments, soft tissues, and bones around your shoulder.

**Implant Material**

The materials within your medical device may be constructed from the following: Ultra-High Molecular

Weight Polyethylene, Stainless Steel Alloy, Cobalt Chrome Alloy, Titanium alloy, Hydroxyapatite or Unalloyed Titanium.

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**

You should have received a set of instructions from your doctor. These instructions may include exercises, therapies, and any limitations on your activities. It is very important that you follow your doctor's instructions. Your doctor will provide 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 issues. 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 issues if your technician is unaware of your implant. This will allow them to manage your MRI scan safely. Your doctor can locate additional information in the Instructions for Use (IFU) provided with the device.

**Possible Side Effects / Risks**

Your doctor will provide information about the side effects of your operation. All operations have risks. The risk of a serious issue is low. There is a risk that you may require additional operations or treatments for several reasons. Please talk to your doctor if you have concerns about your shoulder joint or arm.

Possible risks may include:

- Infection
- Pain
- Joint stiffness
- Joint dislocation
- Decreased movement
- Limb lengthening/shortening
- Implant loosening
- Implant wear
- Ligament or soft tissue disruption
- Bone fracture
- Hardening of muscle (due to calcium deposits)
- Allergic reaction

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.

Receiving a shoulder joint replacement is a major operation. Most people have a good result. However, results vary, and you may have issues. Things such as your anatomy (your size and shape), medical condition, lifestyle (for example, weight and activity level) and surgery affect the result.

Implant lifetime is the time from implantation of your implant to when part (or all) of your implant is removed from your body. Some countries have registries which track the performance of shoulder implants. This registry data was reviewed. The data shows that for a person's total shoulder operation generally 95% (95 out of 100) last more than 7 years. This means that at 7 years about 5% (5 out of 100) of patients may have had additional operations to remove part(s). Hemi-shoulder replacement and revision shoulder replacement have a higher risk of additional operations. Your implant lifetime may be longer or shorter than the average. It is not possible to tell if you will have issues which may require additional operations. The lifetime for your implant depends on your specific medical needs. Your surgeon has access to data 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 shoulder 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**

Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes

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**List of Products**

Delta CTA
Delta Xtend
Global Advantage
Global AP
Global CAP
Global FX
Global Unite
Global ICON

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