Patient Information Leaflet for Sternal Implant

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 implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Implant Description

Sternal implants are used for the fixation of sternal halves.

Implant Material

Your implant material is made of PEEK (Polyetheretherketone).

Information for Safe Use

Make sure you should follow your doctor's advice after surgery. Not following your doctor's advice may result in complications and the need for additional operations.

Discuss any questions, concerns, or potential side effects with your doctor.

This implant is MR safe after the stainless-steel needle is removed.

If you are asked to go for an MRI scan, please show your implant card to the doctor and MRI technician. This will allow them to manage your MRI scan safely.

If you do need a Magnetic Resonance Imaging (MRI), you should let your doctor know about any previous surgeries.

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.

Possible risks may include:

- Problems resulting from anaesthesia (numb sensation in certain areas of the body or induce sleep) and patient positioning (e.g. sickness, vomiting, dental injuries, neurological impairments, etc.)
- Thrombosis (blood clots blocking your blood vessels)
- Embolism (blocked artery caused by a blood clot or an air bubble).
- Infection
- Excessive bleeding

- Iatrogenic neural and vascular injury (Accidental nerve or blood vessel damage)
- Damage to soft tissues including swelling, abnormal scar formation
- Functional impairment of the musculoskeletal system (The ability to perform certain body movements may be restricted)
- Allergy or hypersensitivity reactions (Allergic Reaction)

Device specific events:

- Bone loosening
- Malunion (Incorrect alignment of the device) /non-union (A gap in the joint or bone)
- Pain
- Dehiscence (Wound opening)
- Soft tissue damage

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 sternal implant has an expected lifetime of approximately 7 weeks.

Information specific to your implant, such as lot number/serial number and unique device identifier are included on the implant card. This information is also located in the patient records kept by your health care provider.

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 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 product names:

Sternal ZipFix