Patient Information Leaflet for Intramedullary Nail

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

Implant Description

Intramedullary nails are used to stabilise the parts of the bone which have broken, and to allow the bone to heal. It should also help to align the bone in its correct position to allow you to be able to properly use your leg and put weight on the bone.

Implant Material

Your implant material will either be Titanium, a Titanium alloy, Stainless Steel, Ultra-High-Molecular-Weight Polyethylene (UHWMPE), Polyetheretherketone (PEEK), Elgiloy (mix metal containing cobalt, chromium, iron, nickel, molybdenum) or a combination of these materials.

Information for Safe Use

There is nothing for you to do to ensure safe use of this device. You should follow your doctor's advice after surgery.

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

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.

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.

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 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 vein injury)
- Damage to soft tissues incl. swelling, abnormal scar formation
- Functional impairment of the musculoskeletal system (The ability to perform certain body movements may be restricted)
- Sudeck's disease (Osteoporosis – loss of bone)
- Allergy/hypersensitivity reactions (Allergic Reaction)
- Compartment syndrome (increased body pressures) and side effects associated with hardware prominence
- Malunion (Incorrect alignment of the device) /non-union (A gap in the joint or bone)

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

After bone healing, the removal of the implant is determined by your doctor, and this can be many years after your surgery. These timelines will depend on the device being used, the bone fractured, the method of treatment, and your underlying health.

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 implant, 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:

Expert Nails

Femoral Recon Nail Advanced System

TFNA

Proximal Femoral Nailing System

PFNA

Multiloc

RFNA

TFN