Patient Information Leaflet for Bone Distractor - CMF

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

Implant Description

Distractors are used to stabilise and lengthen bone.

Implant Material

Your implant material will be of the following:

Commercially Pure Titanium

Titanium alloy

Alloy L605

Nickel cobalt alloy

Cobalt chromium molybdenum alloy

Silicone

Stainless steel

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.

Where appropriate, a supplemental Patient Care Guide may be provided to help record and monitor device activation. Ensure the instructions in the Patient Care Guide are followed.

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

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.

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.

General 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
- Injury of critical structures including blood vessels
- Excessive bleeding
- 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)
- Pain
- Discomfort or abnormal sensation due to the presence of the device
- Allergy or hypersensitivity reactions (Allergic Reaction)
- Side effects associated with hardware prominence
- Loosening, bending or breakage of the device
- Malunion/non-union or delayed union, which may lead to breakage of the implant (Incorrect alignment of the device or a gap in the joint or bone)
- Reoperation

Device Specific possible risks may include:

- Bone breakage or bone resorption
- Inflammatory response
- Neurological complications (eg. sensory disturbance, paresthesia).

These risks may require additional operations or treatments. This list does not include all risks. Each type of implant has its own possible specific adverse events. Your doctor can further explain the risks of your operation specific to your implant.

Expected Implant Lifetime and Follow Up

The lifetime of the device ends when it is removed, this should be determined by your doctor and can vary from patient to patient, in some cases this may be up to or over 12 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 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:

Craniomaxillofacial (CMF) Distraction System

Curvilinear Distraction System

Maxillary Distractor

Internal Midface Distractor

Alveolar Distractor

Transpalatal Distraction System