Patient Information Leaflet for Bone Cement - Fractures

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

Your bone cement implant is used to treat arm and leg bone fractures in combination with other fixation devices.

Implant Material

The cement is made of the following material:
Polymer powder (consisting of polymethyl methacylate/acrylate, zirconium dioxide, hydroxyapatite and benzoyl peroxide)
Monomer liquid (consisting of methyl methacrylate (stabilised with hydroquinone, and N,N-dimethyl-p-toluidine)

Information for Safe Use

As part of your operation, you should have received from your doctor a set of instructions regarding exercises, therapies, and any limitations on your activities. You should ensure that you attend all appointments.

It is very important you follow your doctor's instructions about how to recover and restart activities, so you can move with less pain or difficulty.
If you have persisting pain, you should let your doctor know.
Healing takes time and your doctor will provide information on what to expect.
Not following the advice may result in problems and the need for additional surgery.

This implant is MR safe however it is only used in combination with metal hardware. Therefore, it is important 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:

- Myocardial infarction (heart attack)

- Cardiac arrest
- Cerebrovascular accident (stroke)
- Pulmonary and/or cardiac embolism (blocked artery in the lungs and/or heart caused by a blood clot or an air bubble)
- Anaphylaxis (acute allergic reaction)
- Loosening or displacement of the implant
- Temporary drop in blood pressure
- Thrombophlebitis (inflammation and pain caused by a blood clot in a vein)
- Hemorrhage (bleeding caused by a ruptured blood vessel) and hematoma (collection of blood outside of blood vessels
- Superficial or deep wound infection
- Bursitis (inflammation of the bursae in the joints)
- Short-term cardiac irregularities
- Heterotopic bone formation (formation of bone in soft tissue)
- Fever due to allergy
- Hematuria (blood in urine)
- Dysuria (painful urination)
- Bladder fistula (abnormal opening in the bladder)
- Nerve entrapment due to extrusion of the bone cement beyond the region of its intended application (nerve pain caused by the migration of bone cement beyond its intended placement)
- Adhesions and stricture of the ileum (narrowing in the small intestine) due to the heat released during polymerization
- Temporary worsening of pain due to heat released during the polymerization
- Hypersensitivity

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 permanently.

Your surgeon will be able to provide more information based on your specific questions or needs.

Information specific to your implant, including the serial number, unique device identifier etc. are included on the implant card as well as within the patient records kept by your doctor.

Make sure you attend follow-up appointments as scheduled by your doctor.

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

Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes

1-5 Khartoum Rd, North Ryde, NSW 2113

Tel: 1300 562 711

List of product names:

TraumaCem