Patient Information Leaflet for Spinal Cement

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

Spinal Cement is a cement which is implanted in the bones of your spine to fill any defects before hardening, thereby providing stabilisation. Your doctor will inject the cement using tools provided in the kit that comes with the cement.

Implant Material

Your implant contains the following materials Methyl Methacrylate, N,N-Dimethyl-p-toluidine, Hydroquinone, Methyl Methacrylate Polymer, Methyl Methacrylate /Methyl Acrylate Copolymer, Benzoyl Peroxide, Barium Sulphate.

The cement is provided as a liquid and powder that are mixed together by the doctor.

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.

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 anesthesia (pain relief) and patient positioning (e.g. sickness, vomiting, dental injuries, neurological (brain, spine, nervous system) impairments, etc.),
- Heart issues
- Blood clots which may block one or more veins
- Drop in blood pressure

- Allergic reaction
- Superficial or deep wound infection
- Inflammation (redness, swelling, pain and feeling of heat)
- Low oxygen levels in the blood
- Breathing difficulties
- Pain and/or loss of function
- Increased body temperature
- Blood in urine or abnormal sensation when urinating
- Intestinal blockage
- Death
- Dysphagia (difficulty swallowing)

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 device is intended as a permanent implant and its potential removal would be based on your doctor's assessment, which can vary from patient to patient.

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 doctor/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:

Confidence