

## **Patient Information Leaflet for Vertebral Body Replacement 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 spinal implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

### **Implant Description**

Vertebral body replacement implants are used to replace the vertebral body following its removal for injury or disease, to provide spinal stabilization.

### **Implant Material**

Your implant may be made of the following: PEEK (Polyetherether-ketone), TAN (Ti-6Al-7Nb), Tantalum, Commercially Pure Titanium (CPTi).

### **Information for Safe Use**

Make sure you 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.

It is important to inform your doctor about implants that you may have before a magnetic resonance imaging (MRI) scan. These implants within the scope of this leaflet are MR conditional and may be safe to have an MRI scan after your surgery under certain conditions.

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. While many possible reactions may occur, some of the most common may include:

- Problems resulting from anaesthesia (pain relief) and patient positioning (e.g. sickness, vomiting, dental injuries, neurological (brain, spine, nervous system) impairments, etc.)
- Thrombosis (blood clot)
- Embolism (blocked blood vessel)
- Infection
- Excessive bleeding
- Iatrogenic neural (brain, spine, nervous system) and vascular (blood vessel) injury
- Damage to soft tissues including swelling, abnormal scar formation, functional impairment of the musculoskeletal system
- Complex regional pain syndrome (CRPS)
- Allergy/ hypersensitivity reactions

- Side effects associated with the implant or hardware loosening
- Malunion/non-union (bone healing in an abnormal position or not at all)
- Ongoing pain
- Damage to adjacent bones, discs, or soft tissue,
- Dural (a layer of tissue covering the brain and spinal cord) tear or spinal fluid leak
- Spinal cord compression (squeezing/ pressure on the spinal cord) and/or contusion (bruising)
- Displacement of the graft or implant
- Vertebral angulation (abnormal angle or bend)

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.

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 doctor/medical team or report the information to Johnson & Johnson Medical Product Safety Department at [productsafetyjjmanz@its.jnj.com](mailto: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

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### **List of Product names:**

XRL

SYNMESH™

X-MESH

ECD – Expandable Corpectomy Device

SYNEX™

Bengal

TV-TEC-216270

Revision: 01

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