BettaTech®

Patient Information Leaflet for Spinal Cage

This leaflet has information about your implant. Please read this leaflet carefully and keep it in a safe place so you can refer to it in the future if necessary. If you have any questions, talk to your healthcare team. All implants have risks and benefits. The name and number of your Spinal Cage can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Product Name

Spinal Cage

Implant Description and Intended Purpose

This device, a PEEK (POLYETHERETHERETHERKETONE) fusion device, is used to stabilise the spine and to encourage bone fusion during the natural healing process after surgical treatment of spinal conditions/injuries.

The device should only be installed by a surgeon who is trained in the surgical and material elements of the implant and who is knowledgeable about its mechanical and material applications and limitations.

Implant Material

Your implant may contain the following materials: PEEK (polyetherether-ketone), Tantalum.

Information for Safe Use

Always follow your doctor's instructions after surgery. Failure to follow your doctor's advice may result in complications or the need for additional surgery. Talk to your doctor about any questions, concerns and possible side effects.

Magnetic Resonance Imaging

Before having a magnetic resonance imaging (MRI), it is important to inform your doctor about the possibility of implants. The implants included in the scope of this leaflet are MR conditional and may be safe for post-operative MRI scans under certain conditions. Show your implant card to your doctor and MRI technician when you request an MRI scan. If the technician doesn't know the implant, the MRI scan can interact with the implant and cause problems.

Possible Side Effects / Risks

Your doctor will provide information about the side effects of your surgery. All surgeries have risks. While many possible reactions may occur, some of the most common may include:

- Problems resulting from anaesthesia and patient positioning (e.g., nausea, 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, Sudeck's disease (complex regional pain syndrome CRPS), allergy/ hypersensitivity reactions
- Side effects associated with implant or hardware prominence
- Ongoing pain
- Malunion/ non-union (bone healing in an abnormal position or not at all)
- 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)
- Partial displacement of the graft
- Vertebral angulation (abnormal angle or bend)

These risks may require additional surgeries 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

The device is intended to be used as a permanent implant and its removability is determined by the physician's evaluation, which may 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 effect you believe are a result of your implant, please speak with your doctor/medical team or report the information to Wiselink Group Pty Ltd, Suite 31, 427-441 Victoria Avenue, Chatswood NSW 2067, Australia. Telephone 1300 76 80 90.

List of products

Cervical cage consists of Model CI and model CII, the Thoracic and lumbar cage consists of Model P, model T and Model X.