Patient Information Leaflet for Rod-Based Spinal Systems

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

Implant Description

Rod based systems consist of several components which work together to provide immobilization and stabilisation of spinal segments.

Implant Material

Your implant will be made from one or more of the following:

Stainless steel alloy, Titanium alloy, Cobalt-chromium-molybdenum, Cobalt-Nickel-Chromium-Molybdenum, Commercially Pure Titanium, PEEK

Information for Safe Use

Your activity level has a significant impact on the success of this surgery. Any activity can increase the risk of loosening, bending or breaking parts of the implant.

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. The implants within the scope of this leaflet are magnetic resonance (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.

Precaution: DePuy Synthes wire, cable or staple products, used in conjunction with the listed product families, have not been tested for safety and compatibility in the MR environment. Please inform your doctor or present your Patient Implant Card.

Possible Side Effects / Risks

Your doctor will provide information about the side effects of your operation. As with all major operations, risks, side effects and adverse events can occur. 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 and patient positioning (e.g. nausea, vomiting, dental injuries, neurological (brain, spine, nervous system) impairments, etc.),
- Thrombosis (blood clot)
- Embolism (blocked blood vessel)
- Bending, breaking, loosening, or fracturing of the implant
- Allergy/hypersensitivity reactions
- Infections and wound-healing issues
- Additional surgeries
- Bone healing in an abnormal position or not at all
- Decrease in density of the bone
- Sudden, short-lasting pain, ongoing pain, discomfort, or abnormal sensations due to the presence of the implant
- Nerve damage due to the surgery or presence of the implant
- Difficulties urinating or defecating, impotence, retrograde ejaculation and paraesthesia (feelings of pins and needles)
- Bursitis (inflammation of fluid-filled sacs which act as a cushion between your bone and soft tissue; redness, swelling, pain, feeling of heat)
- Paralysis (loss of movement or loss of feeling)
- Dural (a layer of tissue covering the brain and spinal cord) tears or spinal fluid leak
- Damage to arteries and veins resulting in bleeding, due to the surgery or presence of the implant; excessive bleeding
- Damage to lymphatic vessels
- Spinal cord damage or impingement (squeezing/ pressure on the spinal cord)
- Bone fractures
- Wearing down or instability within areas around the site of implantation
- 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)
- Side effects associated with implant or hardware prominence,
- Damage to adjacent bones (e.g. subsidence), disc (e.g. adjacent level degeneration), or soft tissue,
- Partial displacement of the graft,
- Vertebral angulation (abnormal angle or bend)
- Loss of normal spinal contours
- Discontinued growth of the fused portion of the spine
- Pulmonary (lung) complications

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

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.

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.

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

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List of products

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