Patient Information Leaflet for Cranial Mesh

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

Meshes are used for cranial closure and/or bone fixation.

Implant Material

Your implant is made from Pure Titanium, Ultra-High Molecular Weight Polyethylene or Poly (L-lactide-co-glycolide).

Information for Safe Use

Make sure you should 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.

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.
If you do need a Magnetic Resonance Imaging (MRI), you should let your doctor know about any previous surgeries.

RapidSorb – This device does not contain any metals. It will not interfere with a medical test like an MRI (magnetic resonance imaging).

SynPOR, Matrix Neuro, Low Profile Neuro - These implants are MR Conditional.

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 (numb sensation in certain areas of the body or induce sleep) and patient positioning (e.g. sickness, vomiting, dental injuries, neurological impairments, etc.)
- Thrombosis (blood clots blocking your blood vessels)
- Embolism (blocked artery caused by a blood clot or an air bubble)
- Infection or injury of other critical structures including blood vessels
- Excessive bleeding

- Damage to soft tissues including swelling, abnormal scar formation, functional impairment of the musculoskeletal system((The ability to perform certain body movements may be restricted)
- Pain, discomfort or abnormal sensation due to the presence of the device
- Allergic reaction
- Side effects associated with hardware prominence, loosening, bending or breakage of the device
- Malunion (Incorrect alignment of the device) /non-union (A gap in the joint or bone) or delayed union which may lead to breakage of the implant
- Reoperation

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.

Rapidsorb - The device will be resorbed by your body within approximately 12 months but this 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 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:

MatrixNEURO Preformed Mesh

SynPOR

Rapidsorb Resorbable Fixation System

Low Profile Neuro™