Patient Information Leaflet for Fast Set Putty Bone Void Filler

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

This implant is designed to repair, restore, or fill the craniofacial skeleton.

Your doctor will choose the appropriate implant to meet your needs. As with any medical treatment, individual results may vary.

Implant Material

This implant is made of Carbonated Apatite (Ca5(PO4)3OH) with 2% poly(L-lactide-co-glycolide) Fibers and 0.2% Sodium Hyaluronate.

Information for Safe Use

There is nothing for you to do to ensure safe use of this device. You should follow your doctor's advice after surgery. Discuss any questions, concerns, or potential side effects with your doctor. This device does not contain any metals. It will not interfere with a medical test like an MRI (magnetic resonance imaging). This device can be used with other surgical implants. If you do need an MRI, you should let your doctor know about any previous surgeries.

Possible Side Effects / Risks

Your doctor will provide information about the side effects of your operation. As with all major surgical procedures, adverse events can occur that are not directly related to the use of the medical device but rather to the surgery itself. 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:

- Foreign body reactions
- Allergic reactions

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 implant is designed to remain in your body permanently.

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 soft tissue reattachment 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 Products

Norian™