Patient Information Leaflet for chronOS 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 soft tissue reattachment implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Implant Description

The chronOS Bone Void Filler family of implants include chronOS Granules Bone Void Filler, chronOS Preforms Bone Void Filler, chronOS Vivify Bone Void Filler and chronOS Inserts Bone Void Filler. These implants are made of an artificial bone substance and are used to temporarily take the place of bone.

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

Implant Material

These implants contain a calcium salt. The salt includes phosphate. The chemical abbreviation for the salt is $Ca_3(PO_4)_2$. Calcium and phosphorus are the main minerals in bone.

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. All operations have risks. The risk of a serious issue is low. 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:

- Malunion/Non-union (Incorrect alignment of the device or a gap in the joint or bone)
- Bone Damage including Fracture during or after surgery, Osteolysis (softening of bone), or Bone Necrosis (bone death)
- Dural Tear/Inflammation (swelling) or Spinal Fluid Leak
- Damage to Vital Organs/Surrounding Structures
- Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction (Allergic Reaction)
- Nerve Compression and/or Contusion (Bruising)
- Soft Tissue Damage

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

The material of this device gets replaced by your own bone over time. The device itself is absorbed by your body. Absorption takes 6 to 18 months.

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

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