

Patient Information Leaflet

CERAMENT BONE VOID FILLER

What is CERAMENT BONE VOID FILLER?

CERAMENT BONE VOID FILLER is a synthetic bone graft substitute, containing calcium sulfate (60%), hydroxyapatite (40%) and C-TRU. C-TRU is an iodhexol containing liquid, which provides enhanced visibility on X-rays and under fluoroscopy.

What is CERAMENT BONE VOID FILLER used for?

CERAMENT BONE VOID FILLER is used for patients that have a bone void/defect, in order to fill the bone void/defect to support bone healing.

When shall CERAMENT BONE VOID FILLER not be used?

CERAMENT BONE VOID FILLER cannot be used in patients that have a hypersensitivity to iodhexol or to any of the excipients, manifest thyroxicosis, local infection at the site of implantation or are pregnant or breastfeeding.

How is CERAMENT BONE VOID FILLER used?

The surgeon will fill the bone void/ defect with CERAMENT BONE VOID FILLER during your surgery.

How does CERAMENT BONE VOID FILLER work?

Over time, CERAMENT BONE VOID FILLER is completely resorbed and remodeled into new bone within 6-12 months after implantation.

Is any special follow-up or monitoring required if you have CERAMENT BONE VOID FILLER implanted?

As CERAMENT BONE VOID FILLER is gradually remodeled into bone, it does not require any further surgical treatment or monitoring, so you will have the routine follow-up appointments after your surgery.

Adverse effects

Implanting CERAMENT BONE VOID FILLER carries the same risks associated with every surgery such as infection, pain, bruising, swelling and bleeding at surgery site.

If CERAMENT was used in proximity to a joint, this might cause an inflammation (redness, swelling, pain) of the joint.

Within soft tissue, CERAMENT may cause an inflammatory reaction (redness, swelling, pain).

In rare cases CERAMENT can lead to a collection of fluid or fluid that leaks from the wound, which is white in color. This "white wound drainage" resolves in most cases within two-three weeks without further treatment.

The risk of having a serious reaction to iodhexol is regarded as minor. However, swelling of the face, tongue, larynx, itchy or swollen skin, or a rash, can all be signs of an anaphylactic reaction.

Seek medical advice if you experience any of these symptoms.

If you experience a serious incident in relation to CERAMENT BONE VOID FILLER, report it immediately to both:

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