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 iohexol containing liquid, which provides enhanced visibility on X-rays and under fluoroscopy. CERAMENT BONE VOID FILLER contains iohexol (220 mg/ mL paste), trometamol (0.6 mg/ mL paste), sodium calcium edetate (0.05 mg/ mL paste) and hydrochloric acid (less than 1 mg/ mL paste).

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.

How does CERAMENT BONE VOID FILLER work?

Over time, CERAMENT BONE VOID FILLER is 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?

No further surgical treatment or monitoring is required, 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 BONE VOID FILLER was used in proximity to a joint, this might cause an inflammation (redness, swelling, pain) of the joint.

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

In rare cases CERAMENT BONE VOID FILLER 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 C-TRU or its excipents (iohexol, trometamol, sodium calcium edetate, hydrochloric acid) 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.

Do you use other medicines?

Tell your surgeon if you are using, have recently used or might use any other medicines.

For Australia: Serious incidents in relation to the device should be reported to complaint@bonesupport.com and to the TGA via www.tga.gov.au