

Patient Information Leaflet

CERAMENT V

What is CERAMENT V?

CERAMENT V is a synthetic bone graft substitute, containing Calcium sulfate (60%), Hydroxyapatite (40%), Vancomycin hydrochloride and C-TRU. C-TRU is an iohexol containing liquid, which provides enhanced visibility on X-rays and under fluoroscopy. CERAMENT V contains iohexol (206 mg/ mL paste), Vancomycin (66 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 V used for?

CERAMENT V is used for patients that have a bone void/defect, in order to fill the bone void/defect to support bone healing and prevent infection.

How does CERAMENT V work?

Over time, CERAMENT V is resorbed and remodeled into new bone within 6-12 months after implantation. The Vancomycin helps to prevent colonization.

Is any special follow-up or monitoring required if you have CERAMENT V implanted?

No further surgical treatment or monitoring is required, you will have the routine follow-up appointments after your surgery.

Does the Vancomycin in CERAMENT V mean I don't have to take antibiotics separately?

No. If you have been prescribed antibiotics following your surgery, you must take them, as the Vancomycin in CERAMENT V does not replace the need for oral or intravenous antibiotics.

Adverse effects

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

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

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

In rare cases CERAMENT V 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, Vancomycin or their excipients (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