Patient information Leaflet for G1 / G3 bone cement

What is in this leaflet?

This leaflet answers some common questions about G1 / G3 bone cement. It does not contain all the available information. It does not take the place of talking to your surgeon. All medical devices and implants have risks and benefits. Your surgeon has weighed the risk of using this product against benefits that are expected. Follow your surgeon's advice even if it differs from what is in this leaflet.

What is G1 / G3 bone cement and what is it used for?

G1 and G3 are radiopaque bone cements for surgical use to perform arthroplasty procedures, such as hip replacement, knee replacement, ankle replacement, shoulder replacement and other joint replacements, specifically formulated to allow fixation of prosthetic devices on the living bone. Bone cements G1 and G3 are intended to be used during surgical interventions caused by: arthroplasty revision, joint replacement after a traumatic event, osteoarthritis and osteoporosis hangover.

What is G1 / G3 bone cement made of?

The bone cement is supplied as a two-component system, consisting of separate, sterile liquid and powder components, which are mixed together at the point of use to produce the cement

How is the G1 / G3 bone cement used?

The preparation, handling and application of G1 / G3 bone cement must be performed only by qualified healthcare professionals, specifically trained in the procedure and under the direct supervision of the physician responsible for the procedure.

For whom is the G1 / G3 bone cement used?

G1 and G3 are radiopaque bone cements are used for patients whose general skeletal growth is completed.

When should G1 / G3 bone cement not be used?

Do not use G1 / G3 bone cement in the following cases:

- hypersensitive to the constituents of bone cement or to the contrast medium (barium sulfate).
- local or systemic infections not completely resolved.
- during the first trimester of pregnancy.

Warnings

- Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds following the application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement.
- Rare severe adverse events, associated with the use of bone cements include myocardial infarction, cardiac arrest, cerebrovascular accident and pulmonary embolism.
- The polymerization of bone cement is an exothermic reaction which finishes only when the bone cement becomes hard inside the body. That generated heat may damage bone tissue o other tissues in contact with bone cement.
- The addition of non-approved ingredients (powder, water solutions,…) severely compromises physical and chemical characteristics of bone cement both in the preparation phase and after the implant.
- The safety and effectiveness of G1 and G3 bone cement in pregnant women or children has not yet been established. Bone cement must not be used during the first trimester of pregnancy. During all other stages of pregnancy, the product must only be used in the case of life-threatening circumstances. Follow your surgeon's advice even if it differs from what is in this leaflet.
- When treating children, G1 and G3 bone cement can be used to save limbs only in the event that other treatment procedures will not have a good probability success. Follow your surgeon's advice even if it differs from what is in this leaflet.

Precautions

- This device cannot be reused or re-sterilized.
- G1 / G3 bone cements must be stored in the sealed original package, inside a dry, clean storage room, at a storage temperature not below 5°C and not above 25°.
- Use always the entire content of one powder bag mixed with the entire content of one single vial.
- The G1 / G3 bone cements cannot be used when the shelf-life indicated has been exceeded.
- G1 / G3 bone cements are provided sterile, opened or damaged packages must be disposed of with all their content.

Expected Device Lifetime

3 years (shelf-life of sterile packaging), no limitations of lifetime in implanted state.

Postoperative adverse effects

A postoperative monitoring must be carried out in consultation with the responsible surgeon.

Reporting adverse effects

If you wish or report any adverse effects you believe are a result of the G1 / G3 bone cements, please talk to:

Manufacturer: G21 S.r.l. Via S. Pertini 8, 41039 San Possidonio (MO) Italy
Email: info@g-21.it
Internet: www.g-21.it

For Australia only:

If any serious incident occurs in relation to your implant either yourself or your surgeon can report the incident to both Sponsor and to the Therapeutic Goods Administration (TGA).
More information can be found at www.tga.gov.au
Sponsor: Lima Orthopaedics Australia Pty Ltd 40 Ricketts Rd Mount Waverley VIC 3149 Australia