Precautions

- This device cannot be reused or re-sterilized.
- V-Steady bone cement 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 V-Steady bone cement cannot be used when the shelf-life indicated has been exceeded.
- V-Steady bone cement is 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 V-Steady bone cement, 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: Orthotech, 51 Sandgate Rd, Albion QLD 4010, Australia

G21
STRENGTH FOR LIFE

Patient information Leaflet for V-Steady bone cement

What is in this leaflet?

This leaflet answers some common questions about V-Steady 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 V-Steady bone cement and what is it used for?

V-Steady is radiopaque bone cements for surgical use to perform percutaneous vertebral augmentation procedures, such as vertebroplasty or kyphoplasty. Bone cement V-Steady is intended to stabilize and reinforce vertebral body structure in percutaneous vertebroplasty and kyphoplasty procedures, when treating painful pathologic compression fractures of vertebral body, which do not respond to antalgic therapy, and are caused by primary and secondary osteoporosis, osteolysis coming from tumors in the vertebral body (metastatic carcinomas or myelomas), osteolysis coming from symptomatic vertebral hemangiomas. It should be observed that vertebral augmentation procedures, such as percutaneous vertebroplasty and kyphoplasty are only palliative treatments for stabilizing the vertebral bodies and release pain. They do not treat the underlying illness (osteoporosis or tumor-related illness).

What is V-Steady 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 V-Steady bone cement used?
The preparation, handling and application of V-Steady 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 V-Steady bone cement used?
V-Steady radiopaque bone cement is used for patients whose general skeletal growth is completed.

When should V-Steady bone cement not be used?
Do not use V-Steady bone cement in the following cases:
- hypersensitive to the constituents of bone cement or to the contrast medium (Zirconium dioxide),
- local or systemic infections not completely resolved.
- pregnancy or breast feeding,
- tumors of vertebral body extended to epidural space,
- tumors extended to spinal canal, with occlusion greater than 20%,
- bone fragment affecting the spinal cord,
- vertebras' anatomic damage causing unsafe access into vertebral body,
- non collaborating patient, patient unable to follow operator's instructions,
- metabolic diseases which interfere with bone cement polymerization reaction,
- osteomalacia,
- non local infection foci potentially interesting implant,
- hypotension,
- congestive heart disease,
- renal failure.

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.
- Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.
- Serious adverse events, some with fatal outcome, associated to the use of bone cements for vertebroplasty or kyphoplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early within the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.
- Other reported adverse events for acrylic bone cements intended for vertebroplasty or kyphoplasty include: Leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.
- Uncompleted filling of vertebral body may imply insufficient symptoms corrections and long term reduced stability of the treated vertebra.
- In case of bone cement leakage outside vertebral body, paravertebral structures may be damaged, potentially causing spinal cord compression, intercostal pain, leakage in the intervertebral space, perivertebral blood vessels filling, with risk of embolism, infections and post surgical pain.
- In case of treatment of hemangioma, a preliminary vascular sclerotization with percutaneous alcohol application may help in preventing bone cement penetration in blood vessels.
- Use always the entire content of one powder bag mixed with the entire content of one single vial. It is not allowed mixing of more than one powder bag and one vial at a time.
- 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.