Patient information leaflet

HighV+®

www.teknimed.com

Name of the device

HighV+®

Model of the device

HighV+® Reference: T040321

Intended Purpose of the device

HighV+® is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.
Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

Kind of patient on whom the device is intended to be used

Patients in need of fixation of pathological fractures of the vertebral body.

Any special operating instructions for the use of the device

Not applicable: the device is not intended to be operated by the patient. The instructions for use of the device only concern the surgeon.

Intended performance of the device

HighV+® cement allows vertebral fracture stabilization, resulting in pain reduction and improvement of quality of life of patients.

Any undesirable side effects that could be caused by use of the device

INTRAOPERATIVE OR EARLY POSTOPERATIVE

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements for vertebroplasty or kyphoplasty include myocardial infarction cement, cardiac arrest, cerebrovascular accident, decrease in blood pressure, pulmonary embolism, sudden death, short-term cardiac conduction disorders 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.
- pneumonia, intercostal neuralgia, pneumothorax, fracture of a pedicle;
- fracture of ribs in patients suffering from diffuse osteopenia, in particular during thoracic vertebroplasty procedures, due to the high pressure exerted downwards while the needle is being inserted;
- leakage of cement into the intervertebral disks;
- leakage of cement into the vascular system
- leakage of cement into soft tissues
- leakage of cement with compression of the spinal cord possibly resulting in paralysis or loss of sensitivity;
- Interactions with other agents: none known to date.
- Methyl methacrylate may cause hypersensitivity among high-risk persons, which can result in an anaphylactic reaction.

POSTOPERATIVE

Collapse of a vertebra adjacent to the injected vertebra due to an

osteoporotic disease.

Any residual risks that could arise due to any shortcomings of the protection measures adopted
Not applicable: No protection measures are needed for this device.

Warnings about risks that could arise from the interaction of the device with other equipment
This device does not need any precautions or measures to be taken with regard to environmental conditions (such as security portals in airports, induction cooking plates, etc.), or any medical examinations (such as CT-scan or MRI imaging).

Precautions and other measures that, because of those risks, should be taken by the patient or a health professional
Not applicable: no precautions are needed.

Nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken

This device is not intended to be removed and does not need any maintenance.

Symptoms that could indicate that the device is malfunctioning
Recurring pain.

Precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned above
In case of emergency or medical question, contact your physician.

Expected device lifetime
Once implanted, HighV+® expected lifetime is 10 years.

Anything that could shorten or lengthen the device lifetime
Not applicable: HighV+® is not intended to be removed and does not need any maintenance.

Precautions and other measures that should be taken at, or near, the end of the expected device lifetime
No precautions should be taken at, or near, the end of the expected device lifetime: HighV+® is not intended to be removed and does not need any maintenance.

Other circumstances in which the patient should contact a health professional in relation to the operation of the device
Not applicable: the patient does not operate the device.

Materials and substances included in the device
Polymethylmethacrylate
Benzoyl peroxide
Barium sulfate
Hydroxyapatite
Methyl Methacrylate
N-N dimethyl-p-toluidine
Hydroquinone

Any manufacturing residuals that could pose a risk to the patient
There is no known patient risk associated with potential residual manufacturing residues.

Incident reporting
Any serious incident that occurs in relation to HighV+® should be reported to TEKNIMED and to the Therapeutic Goods Administration.

Address of the Therapeutic Goods Administration's website
https://www.tga.gov.au/