Vertefix® MV

Instructions for Use

02458-001 Rev 00A

GENERAL INFORMATION

The implantations of IZI Medical products must only be performed by qualified operators having a sound knowledge and full mastery of operative techniques specific to IZI Medical products. Operative techniques may be acquired from the manufacturer or distributors.

The surgeon is responsible for any complications or harmful consequences which might result from an erroneous indication or operative technique, improper use of the equipment and failure to comply with the safety instructions given in the directions for use. Neither the IZI Medical manufacturer nor the authorized IZI Medical representative can be held responsible for these complications.

The product is acrylic cement for use in vertebroplasty or kyphoplasty. It comes in the form of a sterile liquid ampoule and a sterile powder pouch (monomer in liquid form and powder polymer).

COMPOSITION

Powder (20 g):	
Acrylates copolymers (methyl methacrylate, methyl acrylate, n-buyl metacrylate)	67 %
Benzoyl peroxide	3 %
Barium sulfate	30 %

Liquid (9ml):	
Methyl methacrylate	99.1 %
N-N dimethyl-p-toluidine	0.9 %
Hydroquinone	60 ppm

INJECTION KIT

- Osteo-site VCF Kit (sold separately)
- Bevel-tip trocar, 10G or 11G, 125 mm long (sold separately)

INDICATIONS

The Vertefix MV™ 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).

CONTRAINDICATIONS

The use of the Vertefix MV™ osseous cement is contraindicated in patients having one of the following problems:

- Cases of active, suspected or incompletely treated infection
- Coagulation disorders, or severe cardiopulmonary disease
- Spinal stenosis (>20% by retropulsed fragments)
- Compromise of the vertebral fracture due to posterior involvement
- Patient clearly improving on more conservative medical treatment
- Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture
- Non-pathological, acute traumatic fractures of the vertebra
- Vertebral plana (collapse>90%)
- Compromise of the vertebral body or the walls of the pedicles
- Unstable vertebral fractures due to posterior involvement
- Hypersensitivity to one of the constituents of the product.

ADVERSE EVENTS

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;
- collapse of a vertebra adjacent to the injected vertebra due to an osteoporotic disease,
- leak of cement into the intervertebral disks;
- leak of cement into the vascular system
- leak of cement into soft tissues
- leak of cement with compression of the spinal cord possibly resulting in paralysis or loss of sensitivity;

Interactions with other agents: none known to date.

INSTRUCTIONS FOR USE

1. Setting up the trocars

Once the track has been determined by the operator, the trocars are set in place under radioscopic guidance, using a digitizing table with a hoop.

2. Preparation of Vertefix MV™ cement

POWDER:

- Open the blister pack and take out the sterile powder pouch.
- Carefully open the pouch and pour the whole of the powder into the injection kit mixer.

LIQUID:

- Remove the sterile ampoule from the opened blister pack.
- Do not break the ampoule above the mixer (risk of glass fragments falling into the powder).
- Pour the whole of the liquid onto the powder.
- The first drop poured onto the powder is considered as the beginning of the procedure (t0). Mixing must end 30s later (that is at t0+30s) to facilitate the transfer of the cement into the injector.

Warning: do not pour the powder onto the liquid.

If the Osteo-site VCF Kit injection system is used, follow the directions for use mentioned in the instructions for this kit

3. Filling the injector

Transfer the mixture into the injector straight after mixing, when the injector can be easily filled.

4. Setting up and injection

Screw the injection device onto the trocar pre-positioned in situ. The injection of cement must take place under continuous radiological guidance. In order to prevent vascular migrations, it is necessary to set the cement in place during its injection phase.

Injection is to be stopped when the operator estimates that the vertebral filling is satisfactory, or when a risk of leak of cement becomes apparent. Once the body of the vertebra has been filled, insert the mandrel into the trocar used for the injection to prevent cement residues from settling in soft tissues when the trocar is withdrawn.

At a 20°C (68°F) temperature of the operating room and of the equipment, the various phases are broken down as follows:

With a gauge 11 trocar:

- Filling mixer and mixing: 30"
- Transfer to injector and priming phase: 30" - 2' 30"
- Injection phase: 2' 30" - 20' 00" *
- Setting phase: 20' 00" - 29'00''**

*times obtained with the Osteo-site VCF Kit

injection system at 20°C (68°F). They may vary if different systems are used or the cement is injected at a different room temperature.

**test based on the ISO5833 standard
These times are more than sufficient for the operator to conduct continuous radiological checks and perform filling operations over a period of time, thereby avoiding any unwanted migration of the cement.

!! WARNING !!

- The length of phases of application depends not only on room temperature and that of components, but also on the degree of hygrometry in the operating block. A high temperature reduces hardening time. A low temperature extends this time.
- For controlled and optimal use of the Vertefix MV™ cement, the doses are to be stored at the intended operating room temperature (recommended 20°C) for a minimum of 24 hours before use.
- Read instructions carefully prior to use.
- The operator should have specific training and experience to be thoroughly familiar with the properties, handling characteristics, application of the product and percutaneous cement delivery.
- The manufacturer does not recommend a surgical technique: it is the practitioner's responsibility to determine the appropriate use of the Vertefix MV™ and specific technique for each patient.
- Follow cement handling, mixing and preparation instructions carefully.
- It is strictly forbidden to re-sterilize products. Single use only. Sterile only if package is unopened and undamaged.
- Hypotensive reactions have occurred, between 10 to 165 seconds. They have lasted from 30 seconds to 5 minutes. Some patients have progressed to cardiac arrest. For this reason, patients should be monitored carefully for any change in blood pressure during or immediately after the application of bone cement.
- Methyl methacrylate may cause hypersensitivity among high-risk persons, which can result in an anaphylactic reaction.
- Due to insufficient data, the safety and efficacy of this cement has not been established with regard to pregnant women and children.
- We do not recommend using these products on patients that do not suffer from a pathological condition, such as primary or secondary osteoporosis or a tumor. This could impair the ability of the patient to recover using conservative treatment methods.
- Established surgical principles and techniques must be strictly observed. Deep wound infection is a serious postoperative complication that may require complete removal of the bone cement. Deep wound infection may be latent and may not become apparent until several years after the operation.
- Caution should be exercised to prevent excessive exposure to the concentrated fumes of the monomer, which may irritate the respiratory tract, eyes and even the liver.
- Always check the condition of the liquid before carrying out the procedure. Do not use the liquid component if it shows any signs of thickening or premature polymerization. These conditions indicate that the product has not been stored correctly.
- Do not allow the liquid component to come into contact with rubber or latex gloves. The liquid component is a powerful lipid solvent. Should contact occur, the gloves might dissolve, causing tissue damage. Wearing two pairs of gloves may reduce the possibility of hypersensitivity reactions.
- Do not allow personnel wearing contact lenses to be near or involved in mixing of the bone cement.
- Use appropriate imaging techniques to verify that the needle is correctly positioned, that no damage has been caused to surrounding structures, and that the injected bone cement has been correctly located. Use an imaging technique, such as fluoroscopy, to assess the

capacity of the vertebra to contain the injected bone cement.
- Avoid over-pressurizing the bone cement, as this may cause the bone cement to leak beyond the site of its intended application. Cement leakage may cause tissue damage, and nerve or circulatory problems. Excessive pressure can also be applied to the injection device, which could cause it to break.
- Leaks may also occur during injection if the needle is in a vein or if there are undetected microfractures.
- If bone cement is detected outside the vertebral body or in the circulatory system during the procedure, stop the injection immediately.
- The Vertefix MV™ cement provides a sufficient injection time for use through bilateral tracts, with the filling being done consecutively.
- Inadequate fixation or unanticipated postoperative events may affect the cement / bone interface and lead to micromotion between the cement and bone surface. A layer of fibrous tissue may then develop between the cement and the bone. Long-term regular supervision is therefore recommended for all patients.
- The final polymerization stage occurs in situ and is an exothermic reaction with considerable liberation of heat. According to ISO 5833 standard, the temperature can reach 90°C. Maintain the patient's position until the polymerization process has been completed, so as to obtain proper fixation. An additional 1 to 2 hours or more may be necessary, depending on the patient's medical condition and the operator.
- The long term effects of the bone cement in the spine have not been established.
- Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.

PRECAUTIONS FOR USE

- The surgeon must be trained in Vertefix MV™ operating technique and must follow it scrupulously. We therefore advise you observe the preparation times recommended by the manufacturer.
- Adverse effects may occur whenever you fail to comply with the technique guide;
- The application phases of Vertefix MV™ cement have been determined using an injection system recommended by IZI Medical. They may vary depending on the injection system used.
- It is also recommended that the mixing times given should be complied with in order to prevent the polymerization from progressing to such an extent that the cement is no longer fluid enough to allow easy transfer into the injection system, and proper filling of the bone cavities.
- During the application of Vertefix MV™, radiological control is essential so that the operator can follow the progress of the filling and stop the procedure if the slightest leakage of cement is detected.
- A thorough preoperative check-up of the patient must be carried out prior to the operation.
- Make sure the operating room is properly ventilated to eliminate monomer fumes as much as possible.
- The monomer is a volatile and flammable liquid.
- Ignition of monomer fumes caused by the use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported.
- The insertion of a foreign body into the tissues increases the normal risk of infection associated with surgery during the postoperative period.

This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and / or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the

device may lead to injury, illness, or death of the patient.

STERILIZATION

- The liquid component is sterilized by aseptic filtration.
- The bone cement is packaged in a blister sealed with a Tyvek® film that ensures sterility.
- The powder component is sterilized by ethylene oxide. The chemical witness turned green indicates that the product has been exposed to the ethylene oxide sterilization method.
- Prior to using, carefully check the protective packaging in order to ensure that it has not been damaged in a way that could affect its sterility.
- When taking the product out of its packaging, be sure to follow the asepsis rules.
- The cement is delivered sterile and ready for use in the operating room.
- Re-sterilization of the product is strictly prohibited.
- Do not use after the use-by date.
- Disposable. Do not use if the packaging is damaged.

IMPORTANT INFORMATION TO PHYSICIANS

- Percutaneous vertebroplasty or kyphoplasty procedures should only be performed in medical settings in which emergency decompressive surgery is available.
- Adverse reactions affecting the cardiovascular system have been attributed to acrylic cement. Recent data indicate that the monomer undergoes rapid hydrolysis into methacrylic acid, and that a significant fraction of the circulating methacrylate is present in the form of free acid rather than methyl ester. Correlation between changes in circulating concentrations of methyl methacrylate/methacrylic acid and changes in blood pressure has not been established.
- Check for any change in blood pressure during and immediately after application of the osseous cement.
- The doctor is responsible for any complication or harmful consequences, which may result from an erroneous indication or operating technique, from inappropriate use of the material, or non-observation of the safety instructions that figure in the directions for use.
- Additives (such as antibiotics) are not to be mixed with the bone cement, as this will alter cement properties.

INFORMATION TO THE PATIENT

The patient should be informed by the doctor of the potential consequences of the factors mentioned in the following paragraphs: contra-indications and adverse events, that is, those liable to hinder the success of the operation, as well as possible complications which may arise. The patient should also be informed of the measures to be taken to diminish the possible consequences of these factors.

PACKAGING STORAGE

Designation	Powder (g)	Liquid (mL)
Vertefix MV™	20 g	9ml

The cement is to be stored in its original, unopened packaging, in a dry, clean place, away from light and at a temperature of 25°C max. Keep away from any source of flame or ignition.

RECOMMENDATION FOR DISPOSAL

- Allow the cement to harden before disposal with other medical waste. Comply with local regulations in force relating to medical waste for safe handling and disposal of the cement.
- Regarding separate disposal of the liquid or of the powder, comply with local regulations in force relating to handling and disposal of the cement.




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