Package Insert

Device Description:
The Zavation ZVplasty system is designed for use in vertebroplasty procedures for treatment of vertebral compression fractures in the lumbar or thoracic regions brought on by primary or secondary osteoporosis, cancer or trauma. The Zavation ZVplasty system consist of a variety of manual instruments which provide physicians with a means to access the vertebral body with a mechanical device in order to prepare a site for vertebroplasty. Once the site is prepared the Zavation ZVplasty system instruments are used to percutaneously deliver polymethylmethacrylate (PMMA) bone cement to the spine. The Zavation ZVplasty system instruments are to be used with the following previously FDA cleared items, balloon catheter, inflation syringe, vacuum syringe, stopcock, PMMA bone cement, cement mixing system.

Intended Use:
The Zavation ZVplasty (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Materials:
The ZVplasty system instruments are manufactured from stainless steel.

Contraindications:
-Instability
-Infection
-Severe Bleeding
-Known allergies to bone cement
-Pregnancy

Potential Adverse Events: Potential adverse events include, but are not limited to:
-Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae
-Deep or superficial wound infection
-Retropulsed vertebral body bone fragments which may cause injury to the spinal cord or nerve roots resulting in radiculopathy, paresis or paralysis
-Bleeding or hematoma
-Pneumothorax
-Pedicle fracture

Warnings and Precautions:
-Do no use if sterile package is opened or damaged.
-It is important to read the instructions for use, these precautions prior to device operation.
-Use the instrument kit prior to use by date noted on the package.
-Do not use damaged products. Before use, inspect the packaging to verify that no damage has occurred.
-Do not use this product if you have not been properly trained. Physicians using the device should be familiar with the physiology and pathology of the selected anatomy.
-The instruments should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.
-Do not re-sterilize and/or reuse. The instruments are for single use only. Reconditioning, refurbishing, repair, or resterilization of the device to enable further use is expressly prohibited.

Sterilization: The ZVplasty system will be received sterile in sealed sterile packaging.

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation LLC, 220 Lakeland Parkway, Flowood, MS 39232, USA, Telephone: 601-919-1119

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation LLC, 220 Lakeland Drive., Flowood, MS 39232, USA, Telephone: 601-919-1119.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician. LBL-006 Rev1