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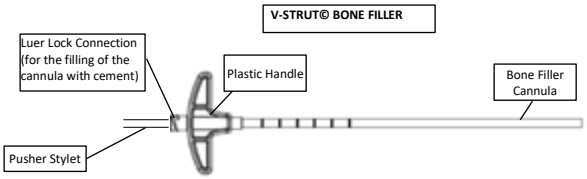
V-STRUT© BONE FILLER
Kyphoplasty bone filler kit

Intended Use: the V-STRUT© BONE FILLER is a needle intended to inject bone cement in the vertebral body in order to restore the morphology of the vertebral body with subsequent stabilization and consolidation of the vertebra during kyphoplasty or vertebroplasty procedure.

CHARACTERISTICS AND PERFORMANCE:
The V-STRUT© BONE FILLER is a cement infusion cannula (often referred to as the "filler" cannula) and consists of a steel cannula (with a plastic handle), that is filled with cement outside the patient and then introduced through the working channel already inserted in the patient, during a kyphoplasty procedure. The device is equipped with a pusher stylet that allows the gradual introduction of the cement into the vertebral body of the patient. The plastic handle has a universal luer cock connection for the filling of the cannula with bone cement.



INDICATIONS:
The device is part of the Kyphoplasty systems used to treat pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

CONTRA - INDICATIONS:
- Infections
- Patients with clotting disorders
- Patients with severe cardiac and / or pulmonary insufficiency
- Patients with known hypersensitivity or allergy to any of the components used in the procedure
- Vertebra plana or circumstances where safe percutaneous access to the vertebra cannot be guaranteed
- Unstable vertebral fractures due to posterior involvement
- Previous damage to the pedicle wall (transpedicular access)
- Lesions that feature narrowing of the spinal canal (more than 20%), including fracture or neoplasm, with or without myelopathy
- Retropulsing vertebral fragments with myelopathy
- A satisfactory response to conservative treatment
- Asymptomatic stable vertebral fractures

Target Patient:
The device is intended for the following patient population:
SEX: Male – Female
MATURATION OF THE SKELETAL SYSTEM: Skeletally mature patients
EXCLUSION: Newborns (<6 months) - Babies (>6 months to 2 years) - Skeletally immature patients

The device is used to treat patients with pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

The patients to be excluded are the followings:
- Patients with infections
- Patients with clotting disorders
- Patients with severe cardiac and / or pulmonary insufficiency
- Patients with known hypersensitivity or allergy to any of the components used in the procedure
- Patients with vertebra plana or circumstances where safe percutaneous access to the vertebra cannot be guaranteed
- Patients with unstable vertebral fractures due to posterior involvement
- Patients with previous damage to the pedicle wall (transpedicular access)
- Patients with lesions that feature narrowing of the spinal canal (more than 20%), including fracture or neoplasm, with or without myelopathy

- Patients with retropulsing vertebral fragments with myelopathy
- Patients with a satisfactory response to conservative treatment
- Patients with asymptomatic stable vertebral fractures

INTENDED USERS AND ENVIRONMENT USE CONDITIONS:

The device is for professional use and, in particular, must be used by qualified and trained radiologists, neuro-radiologists, interventional radiologists, orthopaedic spine surgeons and neuro surgeons, pain therapists.
The professional must have documented basic skills about kyphoplasty.
The device is to be used inside a sterile surgical field such as operating and angiographic rooms.

WARNINGS, PRECAUTIONS AND SIDE-EFFECTS:

- Do not use the instrument if the package is damaged.
- Do not use the instrument beyond the expiry date.
- The device is single-use and must be destroyed after use. Reuse is strictly prohibited. Reuse or resterilization may compromise the structural integrity of the device and/or cause damage to the device which may cause injury, disease or death of the patient. Reuse or resterilization may also create a risk of device contamination and/or cause infection of the patient or cross-infection, including but not limited to transmission of infectious diseases from one patient to the next. Device contamination may cause harm, disease or death of the patient.
- Do not repeatedly test the stylet slide of the bone filler inside the cannula before use
- Do not reuse a component more than once.
- Before injecting the cement (polymethyl methacrylate, PMMA), take a venogram in order to exclude needle positioning directly in the venous complex of the vertebral base. In addition, check the continuity of the posterior vertebral wall by injecting a contrast medium.
- Check that the vertebra are homogeneously filled. The cement should not seep out of the intended space in the veins, discs or epidural spaces.
- The contralateral hemivertebra should be treated in the same way if vertebral filling is less than 50%. Depending on the tolerance of the individual patient, several vertebra can be treated in each single session.
- The system may exclusively be used by physicians. After use, the device may constitute a risk of contamination and/or infection. Therefore, handle with care and dispose of the product in accordance with the regulations in force and medical practice.

In order to minimise the risks or other complications associated with use of the cement for vertebroplasty/kyphoplasty, the following is recommended:

- For all patients that have acute osteoporotic fractures of the vertebral body, a period of conventional treatment should be considered.
- Only qualified and appropriately trained physicians should perform the vertebroplasty/kyphoplasty procedure.
- Use only cements intended for vertebroplasty/kyphoplasty and carefully read the instructions for use of the cement.
- Monitor the procedure using high-quality imaging devices in order to detect PMMA leakage or seepage.
- Closely monitor the patient's blood pressure during and immediately after the procedure; multiple treatments may increase the risk of sudden blood pressure drops due to release of PMMA monomer into circulation. Not more than 3 vertebrae should simultaneously be treated in one session.
- Careful diagnosis should be performed and particular precautions taken if the procedure is performed on patients with spinal tumours that have eroded the posterior wall of the vertebral body.
- It is also recommended not to use the device if particularly risky manoeuvres are necessary where it will be subjected to high torsional or bending forces which might compromise the integrity and proper functioning of the system.
- The procedures must be performed under fluoroscopic guidance with appropriate X-ray equipment.
- It is strictly prohibited to modify, restructure, repair or resterilize the device for reuse.

INSTRUCTION FOR USE

Preliminary operations

- Before use check that the package is not damaged and that the set and its components are not damaged or kinked; if so, inform the manufacturer or your area representative. Take the devices out of the package operating in aseptic conditions.
- Sedate and position the patient. The entire procedure must be performed in real-time under combined computerized axial tomography and fluoroscopic guidance. Digital angiography may also prove useful. Perform local or general anaesthesia.
- Perform the necessary skin disinfection procedures.
- Use in conjunction with a kyphoplasty instrument kit. Prepare the various instruments to be used for the operation. The inflation device, the balloon catheter and the entire kyphoplasty kit may only be used by medical staff.
- Remove the pusher from the filler cannula very gently and slowly, avoiding as much as possible any friction or rubbing between the pusher and the inner wall of the cannula.
- Do not repeatedly test the stylet pusher of the bone filler inside the cannula before use

Instructions

1) Follow the initial step of the kyphoplasty procedure as indicated by the manufacturer of each tool used for the procedure.

2) Inject the bone cement as follows: prepare and mix the bone cement used for the procedure according to the manufacturer's instructions. Fill the Bone Filler Cannula of **V-STRUT© BONE FILLER** with cement and connect it to a dedicated cement injection device at the luer lock connection of the plastic handle of the needle. Insert the Bone filler cannula in the working channel and let the cement flow into the vertebral body by exercising pressure with the Pusher stylet.
3) Extract the V-STRUT© BONE FILLER from the Working channel.

At the end of the procedure extract the Working Channel from the patient following the instructions for use of the manufacturer.

If performing bilateral dilatation, the procedure is similar and to be performed on both sides at the same time.

PACKAGING, STERILIZATION, SINGLE USE
The system is individually packed in rigid PVC blister and medical-grade paper. Do not use the device if the package is open or damaged or contaminated. It is sold in packs of 1 pieces.
The needle is sterilized by Ethylene Oxide (EtO) in compliance with ISO 11135 requirements.
The device is not reusable. The device is single-use and must be destroyed after use.

DISPOSAL:
After use, the device may constitute a risk of contamination and/or infection and puncture or injuries caused by sharp parts of the device. Therefore, handle with care and dispose of the product in accordance with the regulations in force and medical practice.

NOTICE FOR USER AND/OR PATIENT: ANY SERIOUS INCIDENT THAT HAS OCCURRED IN RELATION TO THE DEVICE SHOULD BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND/OR PATIENT IS ESTABLISHED.

Biopsybell declines all responsibility for any damage caused by improper use or different from what is indicated in this instruction leaflet.

Symbol	Description
	Manufacturer
	Catalogue number
	Lot number
	Quantity
	Date of manufacture
	Consult instructions for use
	Caution
	Use by date
	Sterilized using ethylene oxide
	Do not re-use
	Do not resterilize
	Compliant to MDD 93/42/EC
	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Don’t use if the package is damaged
	Keep dry