AUGMENTA™ Vertebral Augmentation System

Instructions For Use

DESCRIPTION

DeGen Medical Kyphoplasty / Vertebroplasty instruments allow for an easy access to the vertebral body through the pedicle. The standard offering consists of three instruments – Guidetube, Stiffener, and Flexible Tamp. There is an optional fourth instrument, the Cement Tube. The Guidetube is a triple prong, Franseen-type tip needle with a low profile handle to facilitate smooth penetration through cortical bone to location of interest and redirection. The Stiffener is bevel shaped, cannulated needle that provides additional support for Guidetube during insertion. The Flexible Tamp creates a void at a determined location. The Cement Tube can replace the Guidetube in delivering bone cement into the void created by the flexible tamp.

FEATURES:

- Franseen tip, triple prong needle allows easy penetration and redirection. A bevel tip option is also available.
- Tactile feedback from Flexible Tamp
- Flexible Tamp reaches 6mm beyond the Guidetube
- Provides full coverage from uni-pedicular approach by creating voids in all quadrants of vertebral body
- Creates predictable voids
- Voids direct cement only where it is needed
- Fracture reduction possible
- Westcott side slot gives precise directional cement flow
- Low profile small handle for ease of use
- Cement chosen by physician preference

INSTRUCTIONS:

1. Make an incision (approximately 1cm) over the target vertebral body.
2. Insert the Stiffener into the Guidetube.
   Note: Align the notch on the side of the Stiffener handle with the notch on the side Guidetube handle. The Guidetube with Stiffener are cannulated for use over a guide wire.
3. Position the Guidetube/Stiffener assembly fluoroscopically over target vertebral position.
4. Push the Guidetube/Stiffener assembly through the vertebral body to create a channel for the Flexible Tamp.
5. Remove the Stiffener from the Guidetube and insert the Flexible Tamp.
   Note: Align the notch on the side of the Flexible Tamp handle with the notch on the side Guidetube handle.
6. Create voids in the vertebral body while continuously monitoring using the fluoroscopic imaging guided Flexible Tamp to compress the necessary cancellous bone.
   Note: Do not twist or rotate the Flexible Tamp, use only a push and pull motion. To reach at all locations around the Guidetube, retract the Flexible Tamp, rotate the Guidetube and push in the Flexible Tamp. After achieving at desired results at that location, retract the Flexible Tamp and redirect the Guidetube at next intended location.
7. After void creation, remove the Flexible Tamp. If Cement Tube is not being used, leave the Guidetube inserted in the vertebral body. Otherwise, remove Guidetube and insert Cement Tube into void.
8. The physician can choose between preferred bone cements of different viscosity and setting times to use with the AUGMENTA device. The Westcott-type side slot allows for bone cement to be released all around the Guidetube and the tip.
9. After cement delivery, remove the Guidetube, or Cement Tube, from the vertebral body.

PRECAUTIONS

- Carefully examine, visually and functionally, the instrument for damage before use. Do not use the device if it is damaged.
- Physician must be knowledgeable of use of the instrument and read the instructions to properly use the instrument. This is a technically demanding procedure presenting a risk of serious injury to the patient.
- The AUGMENTA Vertebral Augmentation System is a single-use device. Reusing this device compromises the safety of the patient by increasing the risk of cross-contamination and infection.
- Re-sterilization, refurbishing, repair or modification of this device is prohibited.
- Use this device only if you have been trained in its use. Prior to use, physicians should be acclimated with the physiology and pathology of the target vertebral body, and have read the instructions to properly use the instrument.
- Always check the position of the Guidetube in relation to the vertebral body using fluoroscopy before creating the channel.
- Components of the device should be fluoroscopically monitored throughout the procedure.
- Use only manual power. Never use any electric power with this device.
- Do not twist the Flexible Tamp, use only a push and pull motion.
- Sharp edges can cause injury to health care personnel.

WARNINGS

- Prior to use, read all package insert instructions and precautions.
- Breakage of the DeGen VA/K system may require intervention or retrieval.
- Do not impact on the instrument for insertion.
- Do not use if patient is known to have allergic reactions to stainless steel.
- Do not use if the site is infected.
- Possible adverse effects - Vertebral fracture, pain, discomfort, vascular injury, nerve injury, infection, spinal cord injury.

STERILIZATION

All instruments used in surgery must be sterilized prior to use. Remove all packaging materials prior to sterilization. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled within the instrument tray(s). Instruments should be positioned to allow the steam to come into contact with all surfaces. Do not stack trays during sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be wrapped in a FDA cleared sterilization wrap and steam sterilized.

The following is the recommended sterilization cycle:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270° F (132° C)
Exposure Time:	4 minutes
Drying Time:	30 minutes

Number of Devices: 4 sets of each component (Guidetube, Stiffener, and Flexible Tamp), a total of 12 components maximum in sterilization case

WARRANTY

The DeGen Medical products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties are hereby disclaimed.

INFORMATION

For further information, please contact customer service via phone or mail at:

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