DI150B-EN (Rev E)	CONTAIN™ VCF SYSTEM

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IMPORTANT INFORMATION ON CONTAIN™ VCF SYSTEM

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For symbols glossary, please refer to www.globusmedical.com/eIFU

ENGLISH

OUTSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE CONTAIN™ VCF SYSTEM

DESCRIPTION

The CONTAIN™ VCF System is designed to contain bone cement injected into bony voids and/or gaps in the vertebral body or other bony structures, to minimize the risk of leakage during and after application. CONTAIN™ is a polyurethane membrane that encases the bone cement. Following fracture reduction and creation of a void, bone cement is injected into the CONTAIN™ Implant, in order to minimize the risk of leakage. CONTAIN™ Implants may be filled with polymethylmethylacrylate (PMMA) bone cement or synthetic bone graft substitutes. CONTAIN™ Implants are sterile, single use devices that are available in different design configurations, each with various sizes to accommodate varying anatomical and surgical needs. The CONTAIN™ VCF System is to be used with the AFFIRM™ VCF System.

INDICATIONS

The CONTAIN™ VCF System is intended to be used for the reduction and fixation of fractures by restricting the flow of bone cement or synthetic bone graft to within a membrane that fills a void in cancellous bone in the spine, hand, tibia, radius, or calcaneus. This includes percutaneous vertebral augmentation. Vertebral compression fractures may result from osteoporosis, trauma, benign lesions and/or malignant lesions such as metastatic cancer and myeloma. The system is to be used with cleared/approved spinal polymethylmethacrylate (PMMA) bone cements or synthetic bone graft substitutes indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

WARNINGS

Please refer to the product insert for AFFIRM™ VCF System that is used in con junction with CONTAIN™ VCF System.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery include:

- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae
- CONTAIN™ device failure due to bone splinters and/or surgical instrument contact
- Deep or superficial wound infection
- Retropathy, paresis, or paralysis
- Bleeding or hematoma.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of spinal fracture.

Do not use this product after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date. Use this device as supplied. Handle the device as per the directions for use provided below.

PRECAUTIONS

Use of the CONTAIN™ VCF System should be performed only by experienced surgeons with specific training in the use of this system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered prior to performing this surgery.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

- CONTAIN™ is designed to be used with PMMA bone cement or synthetic bone graft substitutes. Do not use other filler materials.
- CONTAIN™ is not intended to be altered, trimmed, or cut. Only use this device as supplied.
- The product is provided sterile; do not re-sterilize product.
- Product packaging should always be inspected to ensure integrity. Do not use if packaging has been damaged or the product is expired.
- Do not re-use the product.

CONTRAINDICATIONS

Use of CONTAIN™ VCF System is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials
- Any patient whose activity, mental capacity, mental illness, alcoholism, dry abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses during healing and may be at greater risk of failure
- Bleeding disorder or treatment that increases the chance of excessive bleeding
- Any known severe allergy to device materials or bone cement
- Instability of posterior wall and/or pedicles
- Pedicle fracture
- Epidural abscess
- Sepsis
- Osteomyelitis
- Active infection
- Discitis
- Uncorrectable coagulopathy
- Symptomatic cord compression at the level of fracture
- Severe cardiopulmonary disease
- Pregnancy
- Thrombophlebitis
- Lymphedema

The CONTAIN™ Implant should not be used if the vertebral body, hand, tibia, radius or calcaneus dimensions or fracture pattern do not allow safe placement of the device.

CONTACT INFORMATION

Prior Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

DIRECTIONS FOR USE – CONTAIN™ IMPLANT (PREMIER/ULTRA)

CONTAIN™ Implant

Mandrel Hub Shaft Implantable Membrane

1) Create a cavity in bone using the AFFIRM™ VCF System.
2) Place appropriate sized CONTAIN™ Implant using the insertion mandrel into the anterior end of the cavity through the access cannula and dock the hub onto the cannula hub.
3) Inject appropriate amount of cement/synthetic bone graft substitute into the implantable region following the CONTAIN™ Filler Needle directions for use, provided below.
4) Once the cement/synthetic bone graft substitute is cured, detach the implantable region from the shaft following the CONTAIN™ Detachment Device directions for use, provided below.

DIRECTIONS FOR USE – CONTAIN™ FILLER NEEDLE (PREMIER, 8GA. OR ULTRA, 10GA.)

Needle Plunger Filler Needle

1) Insert the CONTAIN™ Implant into the selected cavity in bone according to the device instructions provided above.
2) Prepare spinal polymethylmethacrylate (PMMA) bone cement with the AFFIRM™ cement mixer pack or prepare the synthetic bone graft substitute according to the manufacturer's instructions.
3) Separate the needle plunger from the CONTAIN™ Filler Needle and load the filler needle with cement/synthetic bone graft substitute according to the device instructions.
4) Insert the filler needle into the CONTAIN™ Implant through the hub.
5) Inject the appropriate amount of cement/synthetic bone graft substitute into the implantable portion of the CONTAIN™ Implant with fluoroscopic guidance by pressing the needle plunger through the filler needle.
6) Repeat steps above when necessary. Once cement/synthetic bone graft substitute delivery is completed, remove the filler needle.
7) If the AFFIRM™ Cement Injection Pack or the AFFIRM™ Extension Delivery Pack with the reusable AFFIRM™ Cement Gun is used, follow the steps below.
   a) Load the syringe with cement/synthetic bone graft substitute according to the device instructions.

b) Attach the syringe to the proximal end of the extension tube. Separate the needle plunger from the filler needle and attach the distal end of the extension tube to the luer of the filler needle. Fill the filler needle with cement/synthetic bone graft substitute by rotating the syringe handle until the cement/synthetic bone graft substitute begins to be ejected from the distal tip of the needle.

c) Insert the filler needle into the CONTAIN™ Implant through the hub.

d) Inject appropriate amount of cement/synthetic bone graft substitute into the implantable portion of the CONTAIN™ Implant with fluoroscopic guidance by rotating the syringe handle. Once cement/synthetic bone graft substitute delivery is completed, remove the filler needle.

DIRECTIONS FOR USE – CONTAIN™ DETACHMENT DEVICE

Obturator Detachment Device

1) Allow cement/synthetic bone graft substitute to cure in the implantable portion of the CONTAIN™ Implant.
2) Separate the obturator from the detachment device.
3) Insert the detachment device into the CONTAIN™ Implant through the hub. Advance until the device handle touches the hub.
4) Fully insert the obturator in the detachment device and rotate until the implantable portion of the CONTAIN™ Implant is completely detached.
5) Remove the obturator and withdraw the detachment device gently with the hub/shaft.

CEMENT INJECTION VOLUMES

Description	**Recommended Cement* Injection Volume**
CONTAIN™ Implant, Premier, 10P	3cc
CONTAIN™ Implant, Premier, 15P	3cc
CONTAIN™ Implant, Premier, 5cc	5cc
CONTAIN™ Implant, Ultra, 10U	3cc
CONTAIN™ Implant, Ultra, 15U	4cc

**or bone graft substitute*

STERILIZATION

The CONTAIN™ VCF System is sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. The expiration date is provided on the package label. Do not use if expired. These components are considered sterile unless the packaging has been opened or damaged.

STORAGE

The CONTAIN™ VCF System should be stored in its original shipping materials. Proper care should be taken to ensure that the system components will be not damaged. Store the system in a cool, dry place; 15°C - 32°C (60°F - 90°F).