DI148B-EN (Rev G)	AFFIRM™ VCF SYSTEM – INSTRUMENTS

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GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
USA
Customer Service:
Phone 1-866-GLOBUS1 (OR)
1-866-456-2871
Fax 1-866-GLOBUS3 (OR)
1-866-456-2873

IMPORTANT INFORMATION ON THE AFFIRM™ VCF SYSTEM – INSTRUMENTS

EC REP: AJW Technology Consulting GmbH
Breite Straße 3 40213 Düsseldorf, Germany

CH REP: AJW Technology Consulting GmbH
Kreuzplatz 2, 8032 Zurich, Switzerland

CE 0297

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

ENGLISH

OUTSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE AFFIRM™ VCF SYSTEM – INSTRUMENTS

DESCRIPTION

The AFFIRM™ VCF System instruments are instrument kits or packs which consist of: access instruments (including drills, cannulas. jamshidi needles, and K-wires), biopsy needle, cavity preparation instruments (expanding scraper), sleeve, an inflation device, and cement delivery instruments (cement mixer, cement guns, and filler delivery needles).

The AFFIRM™ VCF System instruments are fabricated from stainless steel and nitinol as specified in ASTM F899 and ASTM 2063, and from polyurethane.

INDICATIONS

The AFFIRM™ VCF System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. Vertebral compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

WARNINGS

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;
- Rupture with fragmentation of the inflatable portion of the IBT resulting in retention of a fragment within the vertebral body;
- Rupture of the IBT causing contrast medium exposure, possibility resulting in an allergic reaction or anaphylaxis;
- For a transpedicular approach, if the pedicle is not large enough or stable enough to withstand the procedure, pedicle fracture may occur;
- Complications that may occur during a parapedicular approach include pneumothorax and bleeding;
- 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;
- Deep or superficial wound infection;
- Retropathy, paresis or paralysis; and
- 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.

PRECAUTIONS

The implantation of the AFFIRM™ VCF System should be performed only by experienced spinal 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 kyphoplasty.

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.

CONTRAINDICATIONS

Use of the AFFIRM™ 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;
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the Kyphoplasty procedure during healing and may be at a higher risk of failure;
- Bleeding disorder or treatment that increases the chance of excessive bleeding;
- Severe osteoporosis, which may prevent adequate fixation.
- Any known severe allergy to contrast material;
- 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; and
- Pregnancy

These instruments should not be used if the vertebral body, hand, tibia, radius or calcaneus dimensions or fracture pattern do not allow safe placement.

CONTACT INFORMATION

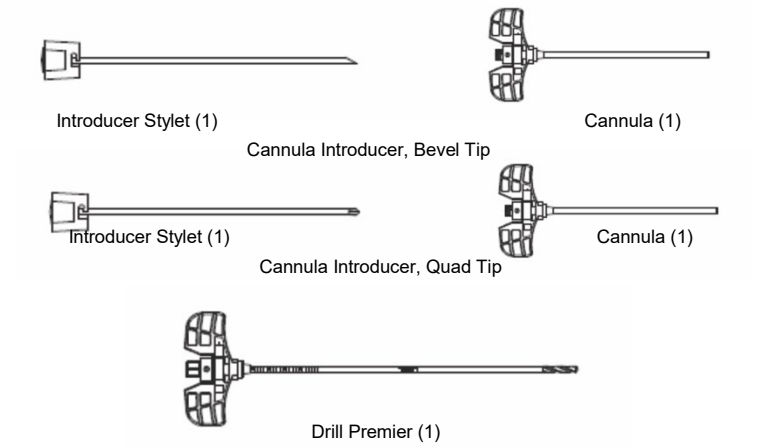
Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

DIRECTIONS FOR USE – ACCESS TRAY OR PACK (PREMIER AND ULTRA)

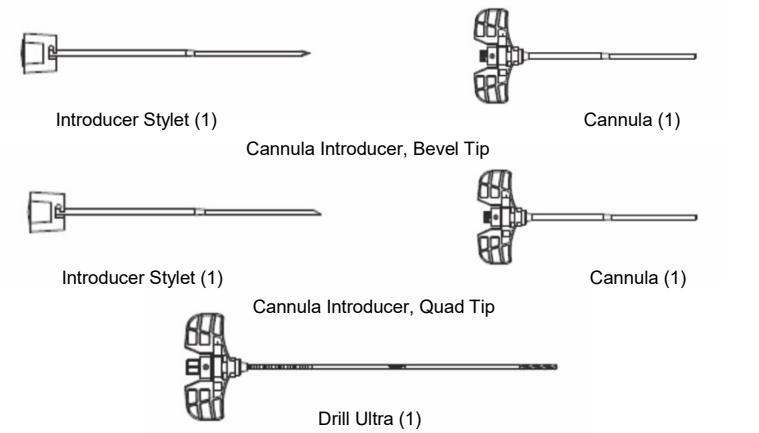
1. Select appropriate access instrument(s).
2. Make an incision on the skin over the selected vertebra using a scalpel.
3. Advance a Cannula Introducer through the soft tissue into the selected vertebra using alternating AP and lateral fluoroscopy as guidance.
4. Remove the Introducer Stylet from the Cannula Introducer.
5. Remove the handle from the Cannula and leave the Cannula in bone.
6. Insert the Drill through the Cannula into the bone to advance the access channel.
7. Drill cautiously with image guidance to the required depth.
8. Remove the Drill once the required depth is reached.

For additional level(s), use Cannulae from the AFFIRM™ Cannula Pack.

AFFIRM™ ACCESS TRAY OR PACK, PREMIER (4.2MM DIAMETER)



AFFIRM™ ACCESS TRAY OR PACK, ULTRA (3.4MM DIAMETER)



DIRECTIONS FOR USE – CANNULATED ACCESS TRAY OR PACK (PREMIER ONLY)

1. Make an incision on the skin over the selected vertebra using a scalpel.
2. Place the Jamshidi Needle though the soft tissue into the selected vertebra, using alternating AP and lateral fluoroscopy as guidance.
3. Remove the Jamshidi Stylet from the Jamshidi Needle.
4. Place a K-Wire through the Jamshidi Needle into the bone with image guidance. Remove the Jamshidi Needle and leave the K-Wire in the bone.
5. Place the Cannulated Introducer over the K-Wire and advance the Cannulated Introducer into the vertebra under fluoroscopy, then remove the K-Wire.
6. Remove the Introducer Stylet from the cannulated Introducer.
7. Remove the handle from the Cannula and the leave the Cannula in the bone.
8. Insert the Drill through the Cannula into the bone to advance the access channel.
9. Drill cautiously with image guidance to required depth.
10. Remove the Drill once the required depth is reached.

For additional level(s), use Cannulae from the AFFIRM™ Cannula Pack.

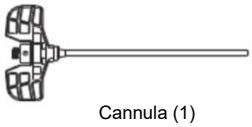
CANNULATED ACCESS TRAY OR PACK (4.2MM DIAMETER)

Jamshidi Stylet (2)

Jamshidi Needle, Premier (2)

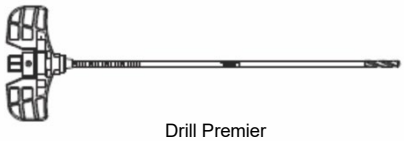
K-Wire, Trocar Tip (2)

Introducer Stylet (1)



Cannula (1)

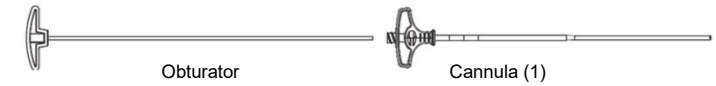
Cannula Introducer, Drill Tip



Drill Premier

DIRECTIONS FOR USE – BIOPSY NEEDLE

1. Use the existing access channel for biopsy collection.
2. Remove the Obturator from the Biopsy Needle.
3. Insert the Biopsy Needle through the access cannula into the vertebra using fluoroscopic guidance.
4. Rotate the handle of the Biopsy Needle for biopsy collection.
5. Remove the Biopsy Needle once biopsy collection is completed.
6. Place the Obturator through the Biopsy Needle for biopsy collection.



Obturator

Cannula (1)

Biopsy Needle (1)

DIRECTIONS FOR USE – EXPANDING SCRAPER

1. Use the existing access channel through for cavity preparation.
2. Attach the Handle to the Expanding Scraper. Insert the Expanding Scraper through the access cannula into the vertebra.
3. Advance the Expanding Scraper into the bone using fluoroscopy to ensure correct placement of the Expanding Scraper.
4. Rotate the knob on the Expanding Scraper counterclockwise to extend the scraper tip into contact with bone under fluoroscopic guidance.
5. Actuate the scraper to prepare the cavity using fluoroscopic guidance. Adjust the angle as necessary.
6. Rotate the knob on the Expanding Scraper clockwise to retract the scraper tip under fluoroscopy. When the scraper tip is completely retracted, remove the Expanding Scraper.

Expanding Scraper (1)

DIRECTIONS FOR USE – SLEEVE

1. If additional reinforcement is desired for the Inflatable Bone Tamp, the Sleeve may be placed over the Inflatable Bone Tamp, prior to inserting into the access channel.
2. Continue to follow instructions for insertion and inflation of the Inflatable Bone Tamp.
3. Remove the Inflatable Bone Tamp and Sleeve prior to injecting cement into the cavity.

Sleeve (1)

DIRECTIONS FOR USE – FILLER DELIVERY TRAY OR PACK

1. Use existing access channels for delivery of bone cement to the prepared cavity.
2. Prepare bone cement in the Cement Mixer according to the mixer manufacturer's instructions and the bone cement manufacturer's instructions.
3. Separate the Needle Plunger from the Filler Delivery Needle.
4. Attach the Filler Delivery Needle to the Mixer and fill with bone cement.
5. Detach the Filler Delivery Needle from the Mixer.
6. To fill multiple Filler Delivery Needles, repeat steps 1 through 5.
7. Place the Filler Delivery Needle through the Cannula into the vertebra and advance the Filler Delivery Needle to the intended location under image guidance.
8. Deliver cement to the intended location of the vertebra by placing the Needle Plunger through the Filler Delivery Needle under continuous fluoroscopic guidance.

Needle Plunger, Premier (6)

Filler Delivery Needle, Premier

OR

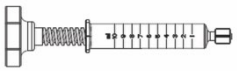
Needle Plunger, Ultra (8)

Filler Delivery Needle, Ultra (8)

DIRECTIONS FOR USE – EXTENSION DELIVERY PACK

1. Use the existing access channel for delivery of bone cement into the prepared cavity.
2. Prepare bone cement in the Cement Mixer according to the mixer manufacturer's instructions and the bone cement manufacturer's instructions.
3. Attach the Syringe to the Cement Mixer.
4. Transfer bone cement to the Syringe.
5. Detach the Syringe from the Cement Mixer. Point the Syringe upward; rotate the plunger to inject cement into the distal end of the Disposable Syringe to remove air.
6. Load the Syringe in the Cement Gun.
7. Connect the fixed end of the Extension Tube to the Syringe.
8. Separate the Needle Plunger from the Filler Delivery Needle.
9. Connect the rotating end of the Extension Tube to the luer port of the Filler Delivery Needle.
10. Purge air from the Syringe and the Filler Delivery Needle by rotating the plunger of the Syringe to inject cement to the distal end of the Filler Delivery Needle.
11. Place the Filler Delivery Needle through the access cannula into the vertebra and advance the Filler Delivery Needle to the intended location under fluoroscopic guidance.
12. Deliver cement to the intended location of the vertebra by rotating the plunger of the Syringe under continuous fluoroscopic guidance.
13. Once cement delivery is completed, remove the Extension Tube and Filler Delivery Needle under fluoroscopy.

Extension Tube (1)



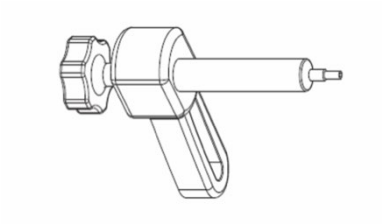
Syringe (1)

DIRECTIONS FOR USE – CEMENT INJECTION PACK

1. Use the existing access channel for delivery of bone cement into the prepared cavity.
2. Prepare bone cement in the Cement Mixer according to the mixer manufacturer's instructions and the bone cement manufacturer's instructions.
3. Attach the Cement Gun with Syringe to the Cement Mixer.
4. Transfer bone cement to the Cement Gun.
5. Detach the Cement Gun from the Cement Mixer. Point the gun upward; rotate plunger to inject cement into the distal end of the syringe to remove air.
6. Connect the fixed end of the Extension Tube to the Cement Gun.
7. Separate the Needle Plunger from the Filler Delivery Needle.

8. Connect the rotating end of the Extension Tube to the luer port of the Filler Delivery Needle.
9. Purge air from the Cement Gun and the Filler Delivery Needle by rotating the plunger of the Syringe to inject cement to the distal end of the Filler Delivery Needle.
10. Place the Filler Delivery Needle through the access cannula into the vertebra and advance the Filler Delivery Needle to the intended location under fluoroscopic guidance.
11. Deliver bone cement to the intended location of the vertebra by rotating the plunger of the Syringe under continuous fluoroscopic guidance.
12. Once cement delivery is completed, remove the Extension Tube and Filler Delivery Needle under fluoroscopy.

Extension Tube (1)



Cement Gun with Syringe (1)

STERILIZATION

The AFFIRM™ instruments and Cement Mixer are sterilized by gamma radiation using a standard medical device sterilization dose of 25-40kGy. This dose was validated using the VD_{Max} method according to ANSI/AAMI/ISO 11137-2:2006 Sterilization of Healthcare Products. Sterilization validation was performed to ensure a sterility assurance level (SAL) of 10^{-6}.

The Inflation Device is sterilized using Ethylene Oxide (EtO) and meets the requirements of ANSI/AAMI/ISO 11135:1994 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. Sterilization validation was performed to ensure a sterility assurance level (SAL) of 10^{-6}.

Some AFFIRM™ instruments are provided NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	25 Minutes	45 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132°C (270°F)	15 Minutes	30 minutes

STORAGE

The AFFIRM™ instruments should be stored in their original shipping materials. Proper care should be taken to ensure that the instruments are not damaged. Store the instruments in a cool, dry place.