DI149A-EN (Rev E)	AFFIRM® VCF SYSTEM – INFLATABLE BONE TAMP
04/2026	**IMPORTANT INFORMATION ON THE AFFIRM® VCF SYSTEM – INFLATABLE BONE TAMP**

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

ENGLISH

WITHIN THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE AFFIRM® VCF SYSTEM – INFLATABLE BONE TAMP

DESCRIPTION

The AFFIRM® Inflatable Bone Tamp is a bone tamp with an inflatable balloon attached to the distal end, designed to create a void in cancellous bone. The Inflatable Bone Tamp is a sterile, single-use device manufactured from polyurethane. The AFFIRM® Curved Bone Tamp is the same AFFIRM® Inflatable Bone Tamp with a curved introduction sleeve.

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;
- Avoid contact between the balloon and the bone cement;
- The balloon component of the Inflatable Bone Tamp may fail due to bone splinters and/or surgical tool contact;
- Do not inflate the balloon until it has been fully deployed in the vertebral body, hand, tibia, radius, or calcaneus. Inflating the balloon prior to full deployment may result in balloon failure due to contact between the balloon and the access cannula;
- 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.

Inflating the AFFIRM® Inflatable Bone Tamp balloon beyond the maximum inflation volume may cause the balloon to rupture before reaching the maximum inflation pressure.

Inflating the AFFIRM® Inflatable Bone Tamp balloon beyond the maximum inflation pressure may cause the balloon to rupture before reaching the maximum volume.

PRECAUTIONS

Use of the AFFIRM® 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 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.

- Never use any gaseous medium to inflate the Inflatable Bone Tamp when it is inside the patient.
- Follow manufacturer's instructions for contrast medium indications and usage. Unintended contrast medium exposure to the patient may occur in the use of the Inflatable Bone Tamp.
- The Inflatable Bone Tamp should only be used when an inflation syringe is attached.
- Inflatable Bone Tamps are intended for single use only. Do not re-sterilize and/or reuse it.
- The inflation characteristics of the Inflatable Bone Tamp are altered by inflation inside the bone.

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;
- Any known severe allergy to contrast material 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; and
- Pregnancy

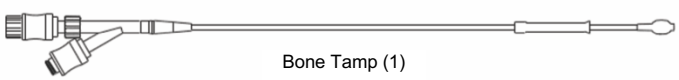
The bone tamp should not be used if the vertebral body, hand, tibia, radius or calcaneus dimensions or fracture pattern do not allow safe placement and inflation of balloon.

CONTACT INFORMATION

Algea Therapies may be contacted at 1-855-639-6612. A surgical technique manual may be obtained by contacting Algea Therapies.

DIRECTIONS FOR USE – INFLATABLE BONE TAMP

1. Use the existing access channel through cancellous bone for cavity creation.
2. Select the appropriate Inflatable Bone Tamp. Fill the Inflation Device with 60% contrast medium according to manufacturer's instructions.
3. Turn the cap of the Stylet to tighten the Stylet into the Inflatable Bone Tamp.
4. Attach the VacLok® Syringe from the Inflation Device Pack to the inflation port of the Inflatable Bone Tamp.
5. Pull the plunger of the VacLok® Syringe back and rotate to lock the plunger in the position of the last slot to remove any air from the Inflatable Bone Tamp prior to use.
6. Detach the VacLok® Syringe from the Inflatable Bone Tamp. Attach the connection port of the Inflation Device to the inflation port of the Inflatable Bone Tamp according to the Inflation Device manufacturer's instructions.
7. Place the Inflatable Bone Tamp through the access cannula into the vertebra and advance to the intended location under fluoroscopic guidance.
8. When using the Curved Bone Tamp, retract the blue sleeve prior to balloon inflation.
9. Use AP and lateral fluoroscopy to ensure desired placement of the Inflatable Bone Tamp. Check the radiopaque band at the distal tip of the Inflatable Bone Tamp on fluoroscopy to verify location.
10. Inflate the Inflatable Bone Tamp to 45psi to secure its position.
11. Inflate the Inflatable Bone Tamp under continuous fluoroscopy until the vertebral body wall or the endplate is touched, or the maximum pressure or maximum volume is achieved, according to the inflation chart parameters listed below. No cortical bone should be perforated. When using the Curved Bone Tamp, move the blue sleeve forward again, covering the balloon, before removing from the cannula.
12. Once inflation is completed, deflate and remove the Inflatable Bone Tamp under fluoroscopy.
13. Proceed to cement delivery.



Bone Tamp (1)

INFLATION CHARTS

AFFIRM® Premier (10P, 15P, 20P) for ø4.2mm working channel

Description	Inflatable Bone Tamp 10P	Inflatable Bone Tamp 15P	Inflatable Bone Tamp 20P
Max. Inflation Volume	4cc ±0.4	4cc ±0.4	6cc ±0.4
Max. Inflation Pressure	400psi (27ATM)	400psi (27ATM)	400psi (27ATM)
Nominal Inflated Diameter	17mm	16mm	17mm
Nominal Inflated Length	20mm	22mm	30mm

AFFIRM® Ultra (10U, 15U, 20U) for ø3.4mm working channel

Description	Inflatable Bone Tamp 10U	Inflatable Bone Tamp 15U	Inflatable Bone Tamp 20U
Max. Inflation Volume	4cc ±0.4	5cc ±0.4	6cc ±0.4
Max. Inflation Pressure	400psi (27ATM)	400psi (27ATM)	400psi (27ATM)
Nominal Inflated Diameter	16mm	16mm	17mm
Nominal Inflated Length	20mm	28mm	30mm

AFFIRM® Curved (10, 15, 20) for ø4.2mm working channel

Description	Inflatable Bone Tamp 10	Inflatable Bone Tamp 15	Inflatable Bone Tamp 20
Max. Inflation Volume	4cc ±0.4	5cc ±0.4	6cc ±0.4
Max. Inflation Pressure	400psi (27ATM)	400psi (27ATM)	400psi (27ATM)
Nominal Inflated Diameter	16mm	16mm	17mm
Nominal Inflated Length	20mm	28mm	30mm

UNCONSTRAINED INFLATION CHART

Ultra 10U (worst case unconstrained test condition)

Description	Inflatable Bone Tamp 10U
Inflation Volume	7cc ±0.7
Inflation Pressure	118psi (8ATM)

STERILIZATION

The AFFIRM® Inflatable Bone Tamp and Sleeve components are sterilized by gamma radiation 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 AFFIRM® Inflatable Bone Tamp should be stored in its original shipping materials. Proper care should be taken to ensure that the Inflatable Bone Tamp will be not damaged. Store the Inflatable Bone Tamp in a cool, dry place; 10°C - 40°C (50°F - 104°F).

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the Order of a Physician.