OSSEOFLEX® SB

STEERABLE BALLOON AND STRAIGHT BALLOON

INSTRUCTIONS FOR USE

Device is sterile. Do not reuse and do not re-sterilize.

INDICATIONS FOR USE

The Osseoflex® SB is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements for use during percutaneous vertebral augmentation, such as kyphoplasty.

DEVICE DESCRIPTION

The Osseoflex SB is designed for use in balloon kyphoplasty or vertebral augmentation. The inflatable bone tamp or balloon serves to create a cavity in the vertebral body, thereby reducing the fracture while still allowing for cement interdigitation. The bone tamp provides a conduit through which the physician can inflate the balloon. After the bone is disrupted, PMMA is injected through an Osseoflex® SN Steerable Needle or an Osseoflex Bone Filler Device to fill the previously created void(s).

An access channel is required for Osseoflex SB placement. The Osseoflex SB device does not create an access channel; the Osseoflex SB is designed to follow a pre-existing channel created by an access channel device.

If the Osseoflex SB Steerable Balloon has an articulating stylet inserted it enables the steerable feature of the balloon. The articulating or steering feature of the device assists the clinician in directing the device through the pre-existing channel. The Osseoflex SB actuation knob can be turned clockwise to aid in directing the distal portion of the device. Turning the actuation knob counter-clockwise will relax the device and allow the device to be returned to its start position.

The balloons should be manipulated only while under fluoroscopic observation with radiographic equipment that provides high quality images.

CONTENTS:

The device package contains (1) Osseoflex SB inflatable bone tamp (10 gauge, 2ml or 4ml balloon size).

Straight OT-0222 or OT-0224

-or-

Steerable OF-0222 or OF-0224

WARNING: Sterilized with electron beam irradiation (IR). Do not use if package is opened or damaged.

WARNINGS / PRECAUTIONS

Thoroughly read the "Instructions for Use" and these warnings and precautions prior to device operation.

- Use the device prior to the "Use By" date noted on the package. 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
- For safe and effective use, this device should only be used by qualified physicians with training in the clinical procedure in which it is being used. The physician should have specific training, experience, and thorough familiarity with the use and application of this product.
- Always use image guidance with radiographic equipment that provides high quality imaging to avoid patient injury. Use appropriate imaging techniques to confirm correct Working Cannula placement (before and during advancement and after removal); absence of damage to surrounding structures, and appropriate location of delivered bone cement. Imaging, such as venography, can be used to assess the ability of the vertebra to contain the delivered bone cement.
- It is essential to maintain a strict sterile technique during the procedure and during all phases of handling this product.
- Dispose of used product per local, state and federal blood borne pathogen controls including biohazard sharps container and disposal procedures.
- DO NOT use if package is opened or damaged. All devices are provided sterile. All devices are sterilized using e-beam radiation. These devices are intended for single use only. DO NOT re-sterilize or re-use. Reconditioning, refurbishing, repair, modification, or re-sterilization of the device(s) to enable further use is expressly prohibited, as it may result in patient injury including loss of function and/or infection.
- The Osseoflex SB should only be inflated using an inflation device.
- Inflating the vertebral balloon beyond the maximum inflation volume may cause the balloon to rupture before reaching the maximum inflation pressure of 400 psi.
- Deflate the balloon before removal. Use the inflation syringe to withdraw contrast from the balloon before removal.
- If using the Osseoflex SB Steerable Balloon, return the actuation knob to the starting position by turning the knob counter-clockwise before removal.
- Avoid contact between the balloon and the PMMA bone cement
- The balloon may rupture due to bone splinters and/or contact with instruments.
- Do not inflate the balloon until it has been fully deployed in the vertebral body. Inflating the balloon prior to full deployment may result in premature balloon failure due to contact between the balloon and the access cannula.
- Breakage of the device may require intervention or retrieval.
- Never use any air or any gaseous medium to inflate the Osseoflex SB. Use only the recommended minimum 60% contrast medium.
- Follow manufacturer's instructions for contrast medium indications, usage and cautions.
- Clinicians should ensure that patients have no unusual risks for bleeding or infection.
- Patients should have no evidence of active infection.
- Patients should also be free of spinal instability that in the judgment of the clinician would remain after vertebral augmentation, and deemed safe for regional or local anesthesia as determined appropriate by the clinician.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with kyphoplasty or vertebroplasty include:

- Pneumonia
- Intercostal neuralgia
- Collapse of a vertebra adjacent to the one injected, due to an osteoporotic disease
- Pneumothorax
- Extravasation of bone cement into soft tissue
- Fracture of a pedicle
- Compression of the spinal cord with paralysis or loss of feeling

Potential adverse events potentially associated with the use of the (device) include:

- Infection, including deep or superficial wound infection.
- Unintended puncture wounds including vascular puncture and dural tear.
- 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 (device) resulting in retention of a fragment within the vertebral body.
- Rupture of the (device) causing contrast medium exposure, possibly resulting in an allergic reaction or anaphylaxis.
- Deep or superficial wound infection.
- Retropulsed vertebral body bone fragments which may cause injury to the spinal cord or nerve roots resulting in radiculopathy, paresis or paralysis.
- Bleeding or hematoma.
- Incorrect placement of the access cannula / stylet assembly or hand drill, possibly resulting in rupture of the aorta and/or nerve damage.
- Dypsnea
- Rib fracture
- Re-fracture of treated vertebral body
- Paravertebral abscess formation
- Vertebral osteitis
- Hemorrhage
- Hematoma
- Pain

Contraindications

- Instability of posterior wall and/or pedicles
- Should not be used if vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon
- Infection
- Severe bleeding
- Bleeding disorder or treatment that increases the chance of excessive bleeding
- Any known allergy to bone cement
- Any known allergy to contrast material
- Pregnancy

DIRECTIONS FOR USE

CAUTION: Follow the manufacturer's Instructions for Use for the inflation syringe.

CAUTION: Contrast media may have different viscosity and precipitation levels that may cause slower inflation and deflation times. For this reason, the use of at least a 60% contrast medium is recommended.

- Select the Osseoflex SB size and type based on the site and treatment goal. Table 1 defines the inflated diameter (D) and the inflated length (L) of the Osseoflex® SB in 37°C water at inflation volume increments to the maximum inflation volume.

- The dimensions below may vary during product use due to local variation in bone structure

Table 1 - Osseoflex SB (10 gauge) Inflated Dimensions (in 37°C water)

Catalog Number	**OT-0222/OF-0222**	**Inflated Dimensions**		
Size	10mm	Volume	Diameter (D)	Length (L)
Max. Inflation Volume	2ml	2ml	14mm	14mm
Max. Inflation Pressure	400 psi (27ATM)			
Catalog Number	**OT-0224/OF-0224**	**Inflated Dimensions**		
Size	20mm	Volume	Diameter (D)	Length (L)
Max. Inflation Volume	4ml	2ml	13mm	18mm
Max. Inflation Pressure	400 psi (27ATM)	4ml	18mm	21mm

Preparation of Osseoflex SB
- Attach a syringe to the inflation port of the Osseoflex SB and pull the plunger back to remove air from the balloon. Detach the syringe.
- Attach the connecting port on the inflation device tubing to the inflation port on the Osseoflex SB.

Osseoflex SB Insertion
- An access channel is required for the Osseoflex SB placement.
- Follow the "Instructions For Use" for the chosen Osseoflex access instruments to create the access channel in the bone.
- Remove the Insertion Sleeve from the balloon prior to use.
- The distal tip of the deflated balloon has reached the distal end of the working cannula when the distal marker band on the balloon shaft enters the proximal end of the cannula. The balloon has fully exited the working cannula when the proximal marker band on the balloon shaft enters the proximal end of the cannula.
- Insert the deflated Osseoflex SB into the access channel and position it under fluoroscopic image guidance.
- The Osseoflex SB Steerable Balloon has an articulating knob that enables the steerable feature of the balloon.
- Turn the actuation knob on the Osseoflex SB Steerable Balloon clockwise to aid in directing the distal portion of the device.
- Turning the actuation knob counter-clockwise will allow the device to return to its start position.
- The device should be manipulated only while under fluoroscopic observation.

Osseoflex SB Inflation
- Inflate the Osseoflex SB under continuous fluoroscopic image guidance.
- Stop when the treatment goal is achieved or when any part of the inflated Osseoflex SB contacts cortical bone.
- Do not exceed the maximum inflation volume and/or maximum inflation pressure (see Table 1).

Osseoflex SB Removal

CAUTION: Never remove the Osseoflex SB without full deflation of the balloon. Never withdraw the Osseoflex SB against resistance. Determine cause of resistance under fluoroscopy and take any necessary remedial actions.
- Deflate the balloon before removal by pulling the inflation device plunger all the way back and removing all contrast medium from the balloon.
- If using the Osseoflex SB Steerable Balloon, return the actuation knob to the starting position by turning the knob counter-clockwise before removal.
- Remove the Osseoflex SB from the bone with a gentle motion.

Completion of Balloon Kyphoplasty Procedure

Please refer to the Osseoflex SN Steerable Needle "Instructions for Use" for application of bone cement following cavity creation in the cancellous bone.

HOW SUPPLIED

The Osseoflex SB package is supplied sterile in a peel-open package. In the event of damage to the sterile packaging, do not use and notify the manufacturer.

STORAGE

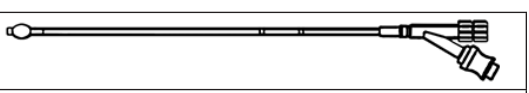
The Osseoflex SB should be stored in its original shipping materials. Proper care should be taken to ensure that the devices will not be damaged. Store in a cool, dry place.

SINGLE USE DEVICE

The reuse of single-use devices can affect the device's safety, performance and effectiveness, exposing patients and healthcare professionals to unnecessary risk. Tissue and organ damage as well as cross-infection can result from the reuse of a single use device. Additionally, reprocessing the device may change the device's physical state, resulting in altered performance, adversely affected safety, and/ or lead to mechanical failure of the device.

STERILE R	Sterilized using Irradiation	EC REP	Authorized Representative in the European Community
	Caution	Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Use By	REF	Catalog Number
	Manufacturer	LOT	Lot Number
	Do Not Use If Package Is Damaged and consult accompanying documents		Consult accompanying documents . For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service
	Keep Dry		Do not resterilize
	Single Use Device, DO NOT REUSE		

PART NUMBER

OT-0222	2ml/10mm	
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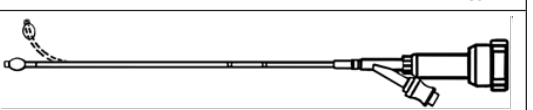
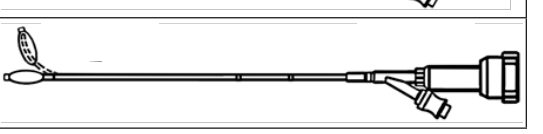
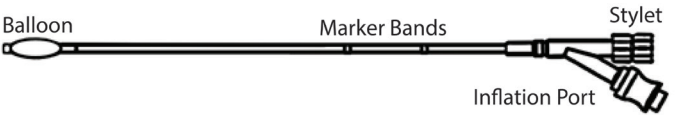
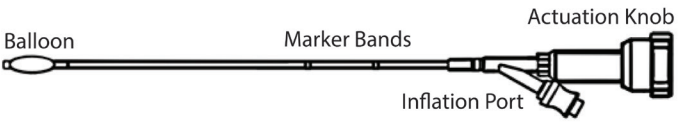
OF-0222	2ml/10mm	
OF-0224	4ml/20mm	

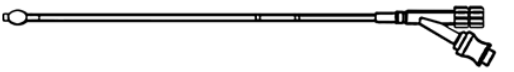
OSSEOFLEX SB STRAIGHT BALLOON	
OT-0222	OT-0224
10 gauge / 2ml / 10mm	10 gauge / 4ml / 20mm



OSSEOFLEX SB STEERABLE BALLOON	
OF-0222	OF-0224
10 gauge / 2ml / 10mm	10 gauge / 4ml / 20mm

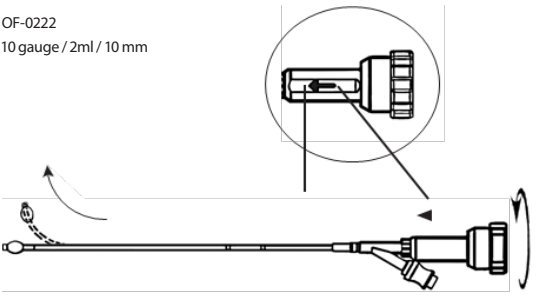


A OT-0222
10 gauge / 2ml / 10 mm



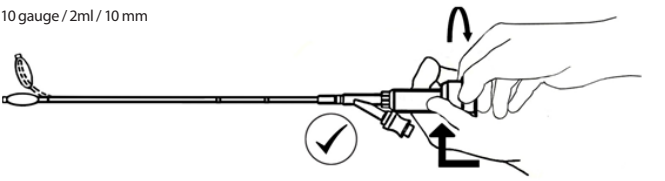
OT-0224
10 gauge / 4ml / 20 mm

B OF-0222
10 gauge / 2ml / 10 mm

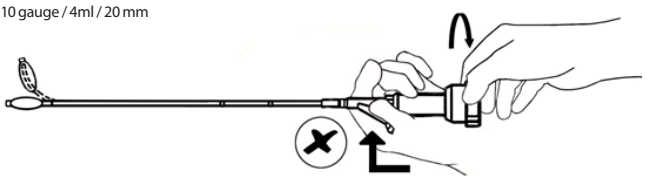


OF-0224
10 gauge / 4ml / 20 mm

C OF-0222
10 gauge / 2ml / 10 mm



OF-0224
10 gauge / 4ml / 20 mm



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