OSSEOFLEX® BFD

BONE FILLER DEVICE

English

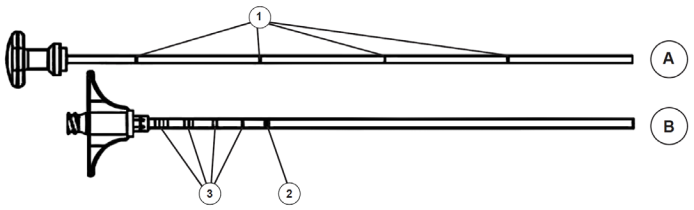
INSTRUCTIONS FOR USE

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE
The Osseoflex® BFD Bone Filler Device is intended for the delivery of bone cement.

DEVICE DESCRIPTION
The BFD package contains (4) Osseoflex BFD Bone Filler Devices - 10 gauge or 8 gauge compatible

Osseoflex BFD Bone Filler Device
OF-0298 / OF-8298



A - Osseoflex BFD Obturator (4)
1 - 0.25cc cement displacement marks
B - Osseoflex BFD Tube (4)
2 - Exit marker
3 - 1cm increment insertion marks

WARNINGS
- The product is sterilized by ethylene oxide. Do not use if package is opened or damaged.
- Breakage of the device may require intervention or retrieval.
- The Osseoflex BFD must be utilized only with the cannula properly positioned in the vertebral body under fluoroscopic guidance using on demand radiographic imaging equipment.
- Following completion of cement delivery, the Osseoflex BFD should be removed before the bone cement polymerizes.
- Do not re-sterilize and/or reuse. The Osseoflex BFD is for single use only. Reconditioning refurbishing, repair, modification, or re-sterilization of the device to enable further use is expressly prohibited as it may result in loss of function and/or infection. It is important to read the Instructions for Use and these precautions prior to device operation.

PRECAUTIONS
- It is important to read the Instructions For Use and these precautions prior to device operations.
- Use the Osseoflex BFD prior to Use By Date noted on the package and verify product is undamaged.
- Physicians using the Osseoflex BFD should be familiar with the physiology and pathology of the selected anatomy, and be trained in the performance of the chosen surgical technique. The device should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.

POTENTIAL ADVERSE EVENTS
Adverse events potentially associated with use of the device include:
- Nerve injury including puncture of the cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Pulmonary embolism
- Hemothorax or pneumothorax
- Infection including deep or superficial wound infection
- Unintended puncture wounds including vascular puncture and dural tear
- Hemorrhage
- Hematoma
- Pain

DIRECTIONS FOR USE
- Fill the BFD tube with bone cement to the distal tip of the tube to purge all air from BFD.
- The 8 gauge compatible BFD tube holds up to 1.0cc of bone cement.
- The 10 gauge compatible BFD tube holds up to .75cc of bone cement.
- Using high quality imaging guidance advance the tube tip through the working cannula to the bone void. Verify placement of tube tip at the intended location under fluoroscopy prior to delivery of bone cement. **NOTE**: The distal tip of the tube has reached the distal end of the cannula when the exit marker on the tube enters the proximal end of the cannula. **CAUTION**: Never deliver cement through the BFD without fluoroscopic guidance to confirm cement position.
- Under fluoroscopic imaging, advance the BFD obturator within the tube by applying manual pressure to the obturator handle to deliver bone cement to the intended location.
- Each indicator mark on the obturator is equivalent to .25cc of bone cement.
- When bone cement delivery is complete, remove the BFD tube and obturator.

HOW SUPPLIED
The Osseoflex BFD Bone Filler Device 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
BFD should be stored in their original shipping materials. Proper care should be taken to ensure that the device will not be damaged. Store in a cool, dry place.

SINGLE USE DEVICE
For single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

STERILE EO	Sterilized using Ethylene Oxide	EC REP	Authorized Representative in the European Community
	Caution: Consult accompanying documents	℞ 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		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		

CE 2797

MERIT MEDICAL®

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