OSSEOFLEX® CD-H

English

HYDRAULIC CEMENT DELIVERY SYSTEM

INSTRUCTIONS FOR USE

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

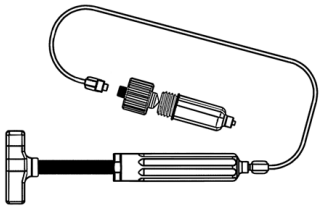
DEVICE DESCRIPTION

Osseoflex® CD-H Hydraulic Cement Delivery System is designed to deliver bone cement away from the radiation source during vertebroplasty, kyphoplasty, or vertebral augmentation and other procedures in the skeletal system.

CONTENTS:

The Osseoflex CD-H Hydraulic Cement Delivery consists of (1) hydraulic syringe, (1) flexible extension tube, (1) cement reservoir, and (1) cement reservoir cap

OF-0348



INDICATIONS FOR USE

The Osseoflex CD-H Hydraulic Cement Delivery System is intended for delivery of bone cement in vertebroplasty, kyphoplasty, vertebral augmentation and other procedures in the skeletal system.

WARNINGS

- Reference the bone cement manufacturer's Instructions For Use for its related warnings, precautions, contraindications and potential adverse events.
- 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 instrument 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.
- The cannula (part of the Osseoflex Access Kit) is not intended for delivering bone cement. Always use the Osseoflex SN Steerable Needle, Osseoflex SN+ Steerable Needle, or Osseoflex BFD Bone Filler Device to deliver bone cement to the vertebral body.
- 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.

PRECAUTIONS

- Examine all packaging prior to opening. DO NOT use device if damaged, or the sterile packaging is breached. Contact the manufacturer if package is opened or damaged.
- Use the device prior to the Use By Date noted on the device packaging.
- Wear safety glasses or a face shield when delivering the bone cement.
- Ensure that all luer-lock connectors are securely tightened. Improperly secured connections could result in disconnection during injection.
- Exercise caution in cases involving extensive vertebral destruction and significant vertebral collapse (i.e., the vertebral body is less than 1/3 of its original height). Such cases may lead to a technically difficult procedure.

POTENTIAL ADVERSE EVENTS

- Serious adverse events, some with fatal outcome, associated with the use of polymethylmethacrylate (PMMA) include:
- Myocardial infarction
- Cardiac arrest
- Cerebrovascular accident
- Pulmonary embolism
- Anaphylaxis
- Diffusion of the bone cement outside the vertebral body: in the peripheral veins (pulmonary embolism), in the epidural plexus (myelopathy, radiculopathy), in the intervertebral disc

The most frequent adverse reactions reported with PMMA are:

- Transitory fall in blood pressure
- Thrombophlebitis
- Hemorrhage and hematoma
- Superficial or deep wound infection
- Bursitis
- Short-term cardiac irregularities
- Heterotopic bone formation

Other potential adverse events reported for PMMA include:

- Pyrexia
- Hematuria
- Dysuria
- Bladder fistula
- Transitory worsening of pain due to heat released during polymerization
- Nerve entrapment and dysphasia due to extrusion of the bone cement beyond its intended application
- Adhesions and stricture of the ileum due to heat released during polymerization

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

CONTRAINDICATIONS

Contraindications for vertebroplasty, kyphoplasty, or vertebral augmentation procedures may include and are not limited to:

- Active Infections
- Hemorrhagic diathesis
- Extended vertebral destruction, destruction of the posterior wall with epidural extension of the pathologic tissue and clinical signs of medullar compression.
- Use during pregnancy, breastfeeding and children. There are no tests which demonstrate the utilization safety during pregnancy or breastfeeding. Device should not be used in the first three months of pregnancy; for the remaining gestation period, should only be used in life-endangering situations. The use in children is advised only when it is believed impossible to operate through other forms of intervention.

DIRECTIONS FOR USE

- Mix bone cement per the manufacturer's Instructions for Use.
- Transfer bone cement to the Osseoflex CD-H cement reservoir up to the start of the threads on the screw cap. Tighten the cement reservoir cap securely by screwing it onto the cement reservoir. Care should be taken to align the cap carefully with the threaded reservoir to ensure proper thread engagement. Verify that the cap is fully tightened before pressurizing or delivering cement.
- A small amount of cement may flow from the tip and should be removed before attaching to the Osseoflex SN or SN+ Steerable Needle.
- Remove the plug from the hydraulic syringe and attach flexible tubing using the female luer connector.
- Attach the flexible tubing to the cement reservoir cap using the male luer connector.
- Firmly attach the cement reservoir to the luer connector on the needle's cement port.
- Turn the handle on the Osseoflex CD-H hydraulic clockwise to advance cement and purge air from the needle before inserting into body.
- Using fluoroscopic visualization, place the needle into the desired location for cement delivery and slowly turn the handle clockwise in half (1/2) turn increments until cement begins to exit from the needle tip.
- Fluoroscopy should be used to confirm the amount of cement introduced to the body. Turn the handle counter-clockwise quickly 3 - 4 turns to relieve pressure or to stop the cement flow.
  NOTE: The Osseoflex CD-H features a pressure relief valve within the water reservoir. The pressure relief valve opens to reduce the pressure within the CD-H when the CD-H reaches its maximum pressure rating. The reduction in pressure will not permit the user to continue to administer cement.
- Following completion of bone cement delivery, remove the Osseoflex SN, SN+ Steerable Needle, or BFD along with CD-H before the cement polymerizes. Immediately insert and lock the stylet in the cannula. If no additional bone cement delivery is required, remove introducer (cannula with stylet).

HOW SUPPLIED

The Osseoflex CD-H Hydraulic Cement Delivery System is supplied sterile in a peel-open Tyvek pouch inside a product box. In the event of damage to the sterile packaging, do not use and notify the manufacturer.

STORAGE

The Osseoflex CD-H Hydraulic Cement Delivery System and its components should be stored in their 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

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 R	Sterilized using Irradiation	EC REP	Authorized Representative in the European Community
	Caution	℞ 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		

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CE 2797

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