OSSEOFLEX® SN & SN+

English

STEERABLE NEEDLES

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION
The Osseoflex® SN and SN+ Steerable Needles are mechanical devices used to disrupt cancellous bone by steering and channeling through the bone creating a void within a vertebral body. The Osseoflex SN and SN+ Steerable Needles can be utilized for multiple level vertebral body access. After the bone is disrupted, bone cement is injected through the Osseoflex SN and SN+ Steerable Needle to fill the previously created void.

CONTENTS: The device package contains: **A or B**

A - (1) Osseoflex SN (10 gauge) or SN+ (8 gauge) steerable needle, (1) biopsy needle, (1) flexible inner stylet and (2) working cannulas, (2) stylets

B - (1) Osseoflex SN (10 gauge) or SN+ (8 gauge) steerable needle

INDICATIONS FOR USE
The Osseoflex SN and SN+ Steerable Needles is used during a vertebroplasty, kyphoplasty procedure to fill a fractured vertebral body with bone cement. Painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma.

CONTRAINDICATIONS
- Spinal cord compression, either acute or progressive
- Vertebral compression due to active or suspected infection
- Traumatic compression in association with a foreign body or projectile, e.g., vehicular trauma, industrial accident or combat injury
- Oncologic applications in which a space occupying mass has replaced part or all of the vertebral body with substantially increased vertebral body mass
- Oncologic applications in which contiguous malignant extension is demonstrated
- Burst fractures, or partial burst fractures in which retropulsed or unstable fragments are present

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
- Re-fracture of treated vertebral body
- Paravertebral abscess formation
- Vertebral osteitis
- Hemorrhage
- Hematoma
- Pain

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 strict sterile technique during the procedure and during all phases of handling this product.
- Precise Working Cannula placement is required for this procedure. Incorrect device placement could result in patient injury.
- The Introducer Stylet must be in place inside the Working Cannula during use of the Introducer (e.g., insertion, removal, manipulation).
- Removal of the Introducer must be performed by rotation and axial motion. DO NOT bend the cannula sideways; patient injury may occur.
- 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 ethylene oxide. 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.
- Clinicians should ensure that patients have no unusual risks for bleeding or infection.
- Patients should have no evidence of active infection.
- Do not use biopsy needle for a sternal procedure. Due to the needle length, internal thoracic organs or blood vessels may be punctured or otherwise damaged.

POTENTIAL ADVERSE EVENTS
Potential adverse events associated with vertebral augmentation, 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 and vasculature
- 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
- 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
- Re-fracture of treated vertebral body
- Paravertebral abscess formation
- Vertebral osteitis
- Hemorrhage
- Hematoma
- Pain

DIRECTIONS FOR USE
- Access the vertebral body using the appropriately sized Osseoflex Access Instruments.
- Obtaining a Biopsy - Optional. Remove obturator from biopsy needle and insert biopsy needle into the access cannula. Using imaging, advance the biopsy needle to the desired depth/location. Rotate the biopsy needle clockwise and counterclockwise sufficiently to dislodge the specimen from the surrounding tissue. Remove the needle from the patient and eject the specimen from the needle using the obturator.
- Insert the Osseoflex SN or SN+ Steerable Needle into the working cannula. The steerable component of the needle should NOT be actuated while in this position. The needle tip will articulate in the opposite direction of the connection port.
- Advance the Osseoflex SN or SN+ Steerable Needle under fluoroscopic guidance into the vertebral body. Activate the steerable component of the needle to create a channel/void by rotating the activation knob clockwise.
- The device has reached full actuation when indication window is fully colored yellow. Turning the knob further may result in device failure.
- If more than one channel/void is desired, de-activate the steerable component of the needle by rotating the activation knob counter-clockwise, retract and re-position the needle in the desired direction of the new channel/void. Do not use a sweeping motion to create a void as it may damage the needle and result in device failure.
- The Osseoflex SN or SN+ Steerable Needle may not be completely straight upon removal once it has been articulated.
- Do NOT unscrew and/or remove the flexible stylet until all channeling, or void creation, has been completed and the physician is ready to inject the cement.
- Once all of the desired channels have been created, remove the Osseoflex SN or SN+ Steerable Needle from the vertebral body. Remove the flexible inner stylet by unscrewing from the cement port.
- The steerable needle component should be fully de-activated any time it is pulled back into the cannula.
- Prepare the bone cement and delivery device according to the manufacturer's Instructions for Use. Prior to connecting cement delivery device to the Osseoflex SN or SN+ Steerable Needle, ensure that no cement is present on the connectors to ensure optimal luer lock connection.
- Connect cement delivery device to the cement port of the Osseoflex SN or SN+ Steerable Needle and purge cement through the needle prior to re-inserting into the vertebral body.
- Re-insert the Osseoflex SN or SN+ Steerable Needle into the working cannula and deploy into the desired location for cement injection.
- Once cement has been injected, de-activate the steerable component of the needle by rotating the activation knob counter-clockwise prior to removal from the working cannula. No color should be visible through the indicator window as shown in Illustration E.
- Following completion of cement delivery, the Osseoflex SN or SN+ Steerable Needle should be removed from the vertebral body prior to the cement polymerizing.
- After concluding the procedure, confirm via fluoroscopy that no portions of the needle remain behind in the vertebral body.

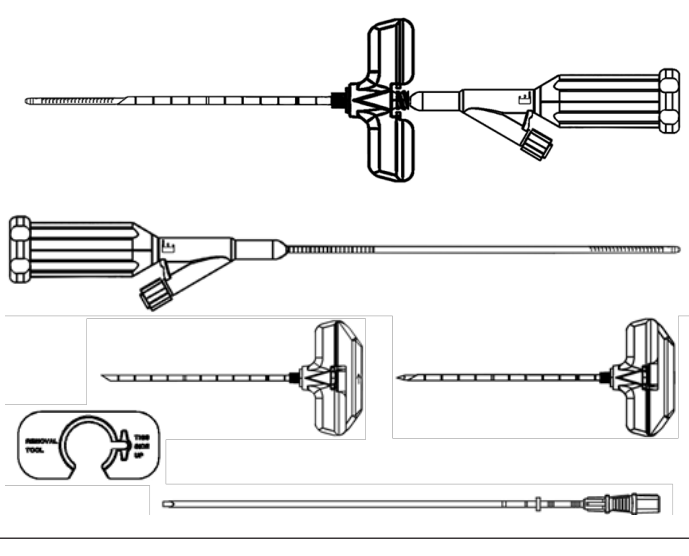
HOW SUPPLIED
The Osseoflex SN and SN+ Steerable Needles are supplied sterile in a peel-open package. In the event of damage to the sterile packaging, do not use and notify the manufacturer.

STORAGE
The Osseoflex SN and SN+ Steerable Needles and their 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.

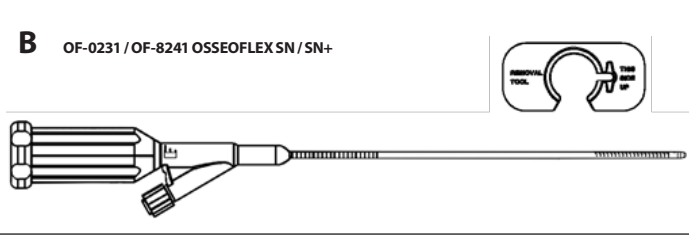
SINGLE USE DEVICE
For single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization 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 EO	Sterilized using Ethylene Oxide	EC REP	Authorized Representative in the European Community
	Caution: Consult accompanying documents	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		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		

A **OF-0020 / OF-0021 OSSEOFLEX SN / SN+**



B **OF-0231 / OF-8241 OSSEOFLEX SN / SN+**



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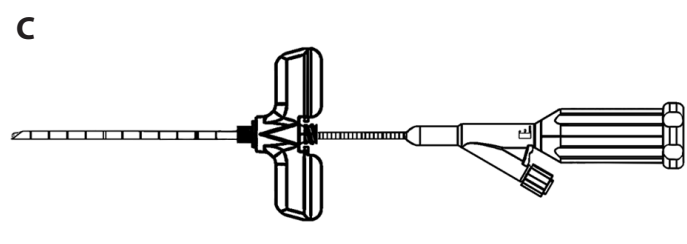

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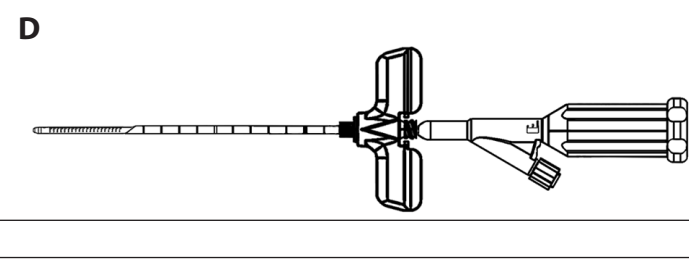

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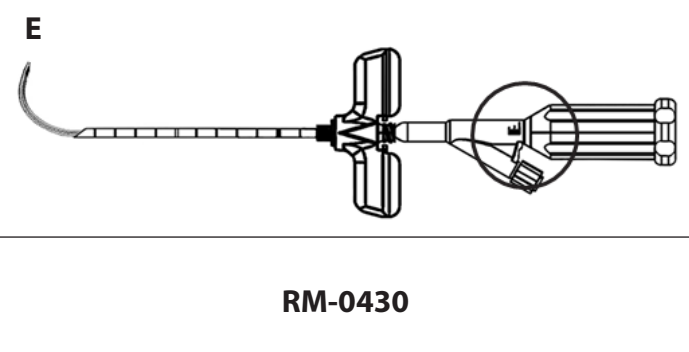
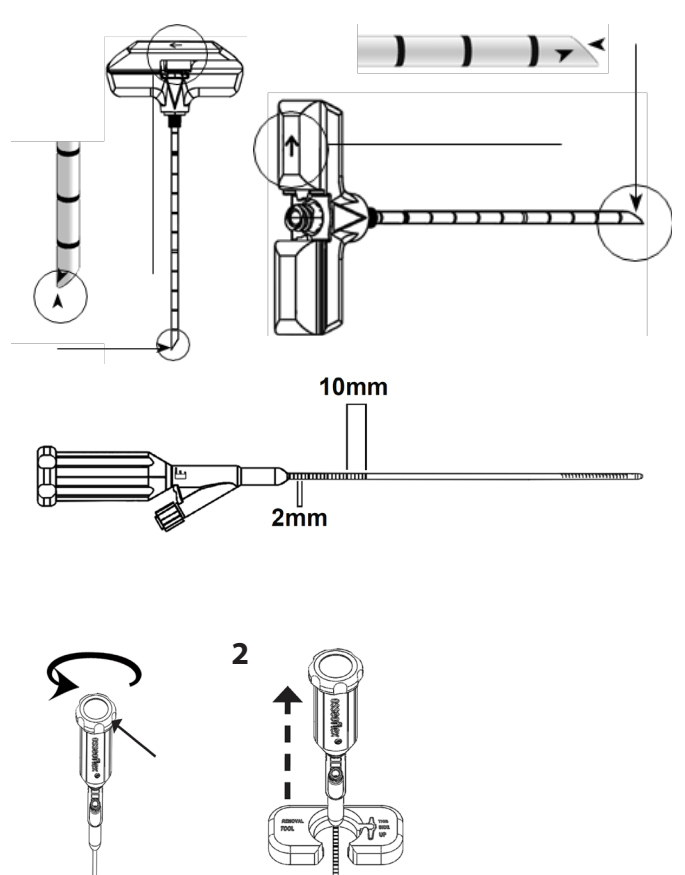
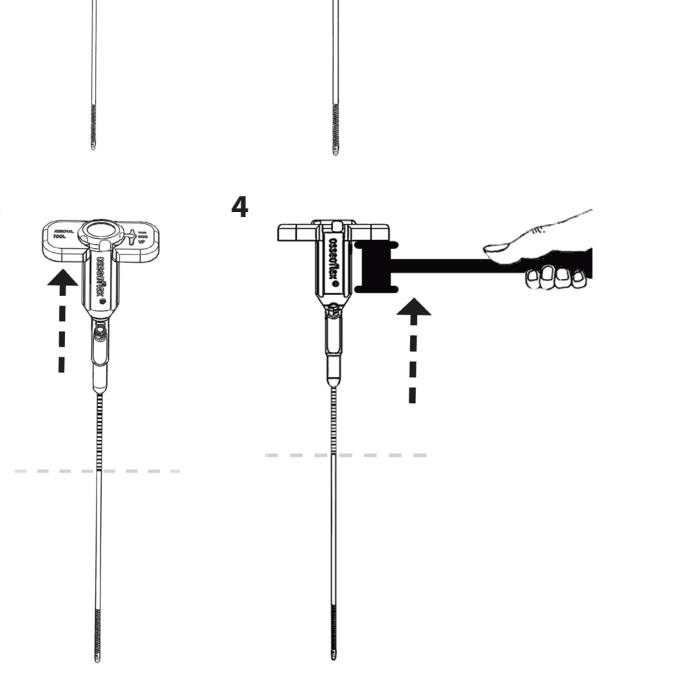


RM-0430





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