OSSEOFLEX®

ACCESS KIT

English

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION
The Osseoflex Access Kit contains:
(1) bevel tip stylet
(1) 4-point diamond tip stylet
(2) cannulas
(1) biopsy needle

INDICATIONS FOR USE
The Osseoflex® Access Kit is intended to be used only for percutaneous access to bone.

WARNINGS
- This device should only be used by qualified physicians with training in the clinical procedure in which it is being used. Always use fluoroscopic guidance to avoid patient injury.
- It is essential to maintain a strict sterile technique during all phases of handling and use of this product. The product is sterilized by ethylene oxide. Do not use if package is opened or damaged.
- Dispose used product per Local, state and federal blood borne pathogen controls including biohazard sharps container and disposal procedures.
- Breakage of the device may require intervention or retrieval.
- The Stylet should be inserted and engaged with the cannula during Introducer access to bone, removal or manipulation.
- Do not re-sterilize and/or reuse. The Osseoflex Access Kit 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.
- 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.

PRECAUTIONS
- It is important to read the Instructions For Use and these precautions prior to device operation.
- Use the Osseoflex Access Kit prior to Use By Date noted on the package to verify no damage has occurred
- Physicians using the Osseoflex Access Kit should be familiar with the physiology and pathology of the selected anatomy, and be trained in the performance of the chosen surgical technique.
- The Osseoflex Access Kit should be manipulated only while 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
- Hemorrhage, hemothorax or pneumothorax
- Hematoma, Infection including deep or superficial wound infection
- Pain
- Unintended puncture wounds including vascular puncture and dural tear
- Any of these adverse events can lead to permanent physical impairment and/or death

DIRECTIONS FOR USE
Bone Access Procedure
- Make a skin incision over the selected area for access.
- Using fluoroscopic imaging guidance, manually advance the stylet and cannula to the selected bone surface checking AP/Lateral images to confirm proper placement. Do not advance the cannula without the stylet fully inserted into the cannula. Rotate the stylet in alternating clockwise and counterclockwise motion to advance the stylet through the bone to the appropriate depth.
- While holding the cannula in place, turn the stylet counter-clockwise to release and remove it from the cannula. The cannula is now ready to accept other instrumentation.

Biopsy Procedure - Optional
- Remove obturator from biopsy needle and insert biopsy needle into the 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.

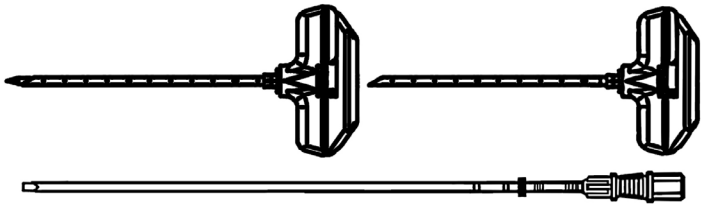
HOW SUPPLIED
The Osseoflex Access Kit is supplied sterile in a peel-open package. In the event of damage to the sterile packaging, do not use and notify the manufacturer.

STORAGE
The Osseoflex Access 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 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		

OS-0001 (10 gauge Access)
OS-8270 (8 gauge Access)



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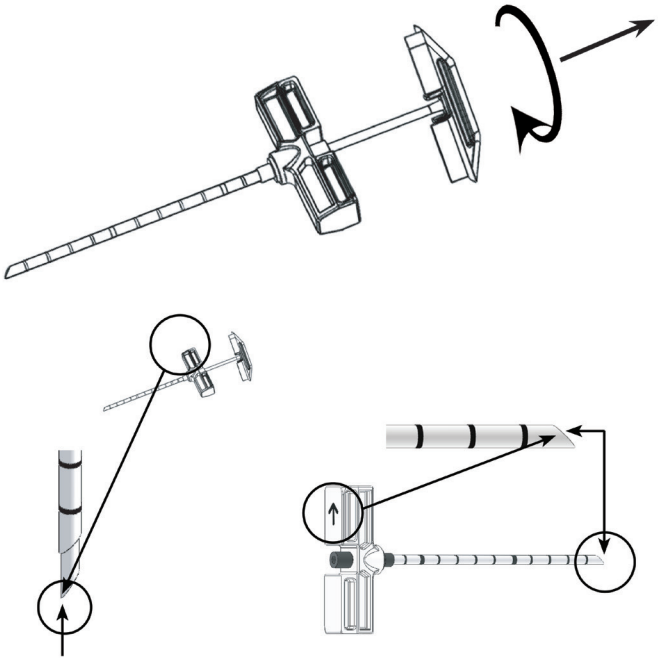

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MERITMEDICAL®

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