OSSEOFLEX®

English

STRAIGHT HAND DRILL

INSTRUCTIONS FOR USE

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

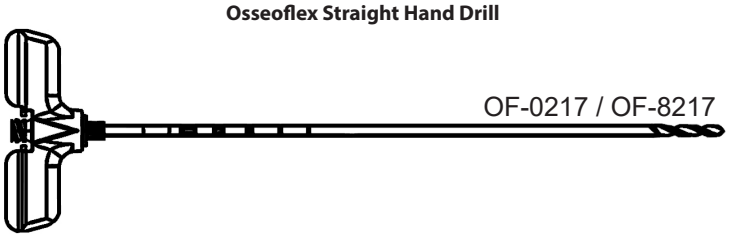
INDICATIONS FOR USE

The Osseoflex® Straight Hand Drill is intended for percutaneous access to bone.

DEVICE DESCRIPTION

The device package contains (1) Osseoflex Straight Hand Drill - 10 gauge or 8 gauge compatible

Osseoflex Straight Hand Drill



WARNINGS

- This device should only be used by qualified physicians with training in the clinical procedure in which it is being used. Always use imaging guidance to avoid patient injury.
- For safe use of the Osseoflex Straight Hand Drill, the physician should have thorough familiarity with the use and application of this product.
- It is essential to maintain a strict sterile technique during all phases of handling and use of this product.
- Dispose used product per local, state and federal blood borne pathogen controls including biohazard sharps container and disposal procedures.
- The product is sterilized by ethylene oxide. Do NOT use if package is opened or damaged.
- Do NOT hammer or bend the device during use. Breakage of the device may occur requiring intervention or retrieval.
- Do NOT re-sterilize and/or reuse. The Osseoflex Straight Hand Drill 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.
- Shaft marks on the drill may be used only as reference marks. Shaft marks are not intended to replace the use of imaging guidance.
- Do NOT use the device without the Osseoflex Access Introducer.

PRECAUTIONS

- It is important to read the Instructions For Use (IFU) and these precautions prior to device operation.
- Use the Osseoflex Straight Hand Drill prior to Use By Date noted on the package.
- Do NOT use damaged product. Before use, inspect the Osseoflex Straight Hand Drill and packaging to verify that no damage has occurred.

POTENTIAL ADVERSE EVENTS

Similar to other alternative devices, adverse events potentially associated with use of Osseoflex Straight Hand Drill include:

- Deep or superficial wound infection
- Unintended puncture wounds including vascular puncture and dural tear
- Hemothorax or pneumothorax
- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism
- Nerve injury including puncture of the spinal cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Pain
- Hemorrhage
- Bleeding or Hematoma

DIRECTIONS FOR USE

- Once cannula is in place, advance the Osseoflex Straight Hand Drill through the cannula into the bone. If needed, see Osseoflex Access Kit Instructions for Use for information on bone access.
- Advance the distal end of the Osseoflex Straight Hand Drill to the DISTAL THICK shaft mark which equals the distal end of the cannula. Confirm this position using imaging guidance prior to proceeding.
- Using manual control and imaging guidance, rotate the Osseoflex Straight Hand Drill clockwise and advance to the desired depth.
- Remove the Osseoflex Straight Hand Drill from cannula by rotating in a counter-clock direction.

HOW SUPPLIED

The Osseoflex Straight Hand Drill 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 Straight Hand Drill should be stored in its 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		

"Founded in 1987, Merit Medical set out to build the world's most customer-focused healthcare company by understanding customers' needs, and innovating and delivering a diverse range of products that improve the lives of people, families, and communities throughout the world .

Merit maintains a diverse, multi-campus manufacturing footprint in North America and Europe with a true global distribution network focused on delivering our products and technologies to our customers."

CE 2797

MERIT MEDICAL®

www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748

EC REP Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland
EC Customer Service +31 43 3588222

403746001_002 2020-09-16