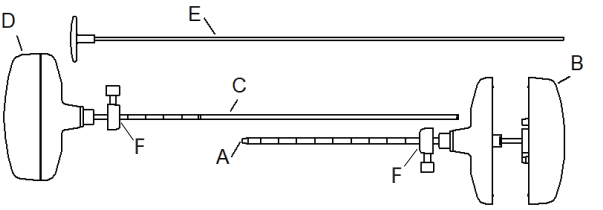
ENGLISH

WESTBROOK™

Bone Biopsy System

INSTRUCTIONS FOR USE



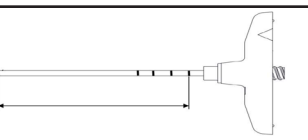
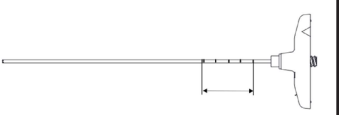
PRODUCT DESCRIPTION

The Westbrook™ Bone Biopsy System is designed for accessing bone and performing bone biopsies. The contents of the system are listed in Table 1. Component working lengths are provided in Table 2.

Table 1: List of components

A	Access Cannula	**D**	Biopsy Handle (with Stiffener)
B	Stylet with Trocar Tip	**E**	Ejector Pin
C	Biopsy Needle	**F**	Sliding Stop (Depth Gauge)

Table 2: Component working length

Component	Working length definition:	Working length size and image:
Access Cannula	Distal tip of the cannula to the proximal laser mark	 KBD1110: 100 mm KBD1115: 150 mm
Biopsy Needle	Distal laser mark to the proximal laser mark	 KBD1110: 50.5 mm KBD1115: 40.5 mm

INTENDED PURPOSE

Bone access and biopsies of bone lesions.

CONTRAINDICATIONS

Contraindicated for use on patients who are receiving heavy anticoagulant therapy or who have a severe bleeding problem. Prior to procedure, patient's medical records should be carefully checked for any history of hemorrhagic activity.

PATIENT POPULATION

For bone access and bone biopsies of lesions in adults.

USER(S)

The device must only be used by a physician trained to carry out biopsies or radiology interventions, or under his/her supervision.

CLINICAL BENEFITS

The intended clinical benefits of the device is reduced morbidity and mortality compared to open surgical procedures.

PERFORMANCE CHARACTERISTICS

- Designed for accessing superficial lesions in soft or normal-density bone. Used with direct access when it is not necessary to cross bony tissue before sampling, this system still allows for multiple, high-grade sampling in mixed-density masses.
- Direct access and comfortable handling
- Fast & efficient penetration of normal-density bone
- High-grade steel for outstanding durability

STORAGE

Store in a cool, dry place (below 26° C), away from humidity and direct heat. Do not use after the expiry date.

PRECAUTIONS

- The device is supplied in a sterile state and should be considered as such unless the packaging has been opened or is damaged. Employ aseptic technique during removal from the package and use. Do not use if the packaging is damaged.
- When in use, only apply pressure with your fingers and ensure that you do not apply excessive axial pressure or bend the elements.
- After use, this product may pose a potential biological risk. All products of this type must be handled and destroyed in accordance with accepted medical practices, legislation and applicable provisions.
- This device includes stainless-steel alloy components that contain Cobalt (EC No.: 231-158-0; CAS No.: 7440-48-4) defined as CMR 1B in a concentration above 0.1% weight by weight.
- In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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.

POTENTIAL COMPLICATIONS

- Biologic Exposure
- Bone Fracture
- Foreign Body Non- Vascular
- Hemorrhage
- Infection
- Inflammation
- Soft Tissue Injury

DIRECTIONS FOR USE

The following is a suggested method for using the device. The approach should be accurately planned using diagnostic imaging and clinically approved techniques. Disinfect the skin, make a small skin incision, and perform anesthesia until in contact with bone. In the case of sclerotic lesions, taking several incremental, smaller, samples are recommended to avoid crushing tissue within Biopsy Needle.

FIG. 1 Depending on the depth of the lesion to be biopsied, adjust the depth gauge on the Access Cannula (A) to the appropriate centimeter marker and tighten to provide a visual guide. Introduce the assembled Access Cannula and Stylet with Trocar Tip (A+B) until bone is reached.
Note: The Access Cannula and Stylet with Trocar Tip (A+B) is not designed for traversing hard bone.

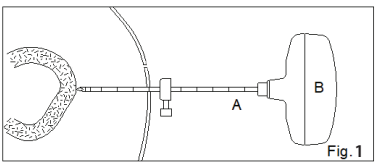


Fig. 1

FIG.2 Hold the Access Cannula (A) firmly against the bone and remove the Stylet (B).

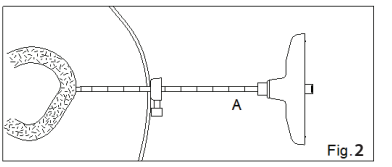


Fig. 2

FIG. 3 Adjust the depth gauge on the Biopsy Needle (C) to the appropriate centimeter marker and tighten to provide a visual guide.
Note: The selected centimeter marker (see Fig. 3) will represent the Biopsy Needle protrusion beyond Access Cannula (A)

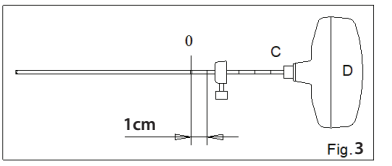


Fig. 3

FIG. 4 Insert the assembled Biopsy Needle and Handle (C+D) through the Access Cannula (A).
Carefully rotate the Biopsy Needle and Handle (C+D) clockwise until desired biopsy depth is achieved (or until the depth gauge of the Biopsy Needle (C) reaches the Access Cannula (A) luer end. Then rotate Biopsy Needle and Handle (C+D) counterclockwise and remove. Remove the Handle (D) from the Biopsy Needle (C); insert the Ejector Pin (E) through the Biopsy Needle (C) from the luer end and eject the sample.
Note 1: Repeat process from Fig.3 if desired and anatomically safe.
Note 2: A syringe can be connected to the luer end of the Biopsy Needle (C) and light aspiration may be applied during removal of the Biopsy Needle (C) if desired.

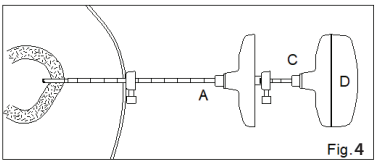


Fig. 4

SYMBOL	DESIGNATION
	Single use
	Do Not Re-sterilize
	Caution: Consult Instructions for Use
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use If Package is Damaged
	Consult Instructions for Use. For electronic copy scan QR code, or go to www.merit. com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
MD	Medical Device
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog Number
	Date of Manufacture
LOT	Lot Number
	Single Sterile Barrier System
	Use-By Date
UDI	Unique Device Identifier
	Contains Cobalt
26°c	Temperature limitation
	Keep away from sunlight
	Keep dry

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