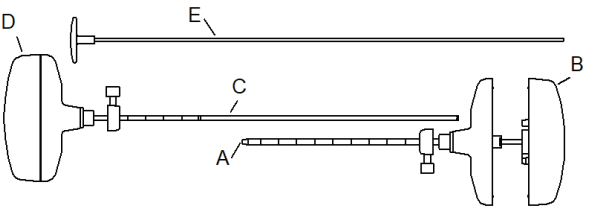
WESTBROOK™

Bone Biopsy System

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The Westbrook™ Bone Biopsy System is designed for accessing bone and performing bone biopsies. The system has the following contents. For specific sizes, see Table #1.

A	Access Cannula	**D**	Biopsy Handle (with Stiffener)
B	Stylet with Trocar Tip	**E**	Ejector Pin
C	Biopsy Needle with Clockwise Tip		

INDICATIONS FOR USE

Bone access and biopsies of bone lesions.

PRECAUTIONS

The device must only be used by a physician trained to carry out biopsies or radiology interventions, or under his/her supervision. The device is supplied in a sterile state and should be considered as such unless the packaging has been opened or is damaged. Do not use if the packaging is damaged. When using equipment from other suppliers, check that their length and diameter are compatible with the components of the device. 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.

STORAGE

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

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.

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.

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.

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 : If you need to pass through hard bone to reach the biopsy area, you must use the corresponding size Merit Preston™ Hard Bone Introducer (provided separately). See included Table #2. The Access Cannula and Stylet with Trocar Tip (A+B) is not designed for traversing hard bone.

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

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. 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.
Note 3: In the case of sclerotic lesions, taking several incremental, smaller, samples are recommended to avoid crushing tissue within Biopsy Needle (C).

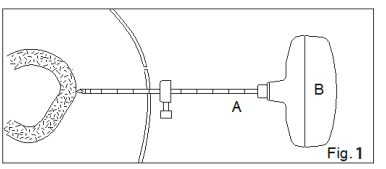


Fig. 1

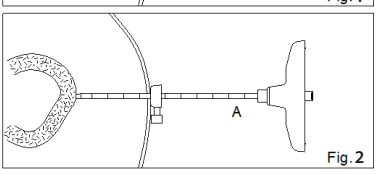


Fig. 2

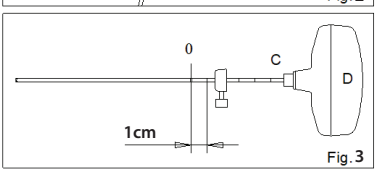


Fig. 3

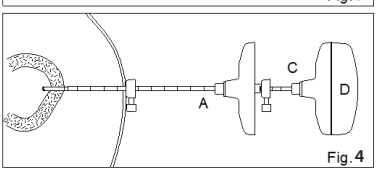


Fig. 4

#1	KBD1110	KBD1115
A	11G x 10cm	11G x 15cm
B	Ø2.3mm x 14cm	Ø2.3mm x 19cm
C	Ø2.35mm x 20cm	Ø2.35mm x 24cm
E	Ø1.7mm x 23.4cm	Ø1.7mm x 27.4cm

#2	KBD1110	KBD1115
	KTP1110	KTP1115

	Single use
	Do not resterilize
	Caution: consult accompanying documents
STERILE EO	Sterilized using ethylene oxide
	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
	Temperature limitation
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.

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CE 2797

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