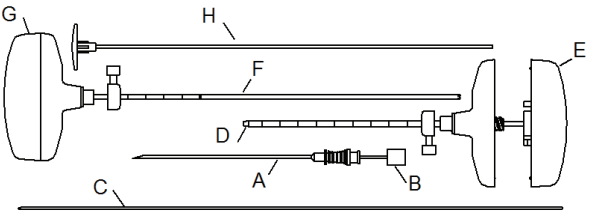
KENSINGTON™

Guide Wire Bone Biopsy System

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The Kensington™ Guide Wire 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	Anesthesia Needle	**E**	Inner Stylet (blunt)
B	Anesthesia Needle Stylet	**F**	Biopsy needle with Clockwise Tip
C	Guide Wire	**G**	Biopsy Handle (with Stiffener)
D	Cannula (blunt)	**H**	Ejector Pin

INDICATIONS

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.

INSTRUCTIONS

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 apply local anesthetic.

FIG. 1 Introduce the Anesthesia Needle and its Stylet (A+B) through the soft tissue until in contact with the bone. **Note**: Perform additional anesthesia with the Anesthesia Needle (A) to the periosteum if desired.

FIG. 2 Withdraw the Anesthesia Needle Stylet (B) and introduce the Guide Wire (C) into the Anesthesia Needle (A) until in contact with the bone.

FIG. 3 Withdraw the Anesthesia Needle (A) while holding the Guide Wire (C) firmly against the bone.

FIG. 4 Place the assembled Cannula and Inner Stylet (D+E) by sliding them over the Guide Wire (C) until in contact with the bone.

FIG. 5 Withdraw the Guide Wire (C). Remove the Inner Stylet (E) while holding the Cannula (D) firmly against the bone.
Note: If you need to traverse hard bone to reach the biopsy area, you must use the corresponding Merit Preston™ Hard Bone Introducer (provided separately, see Table #2). The blunt Cannula and Inner Stylet (D+E) are not designed for piercing or traversing hard bone.

FIG. 6 Adjust the depth gauge on the Biopsy Needle (F) to the appropriate centimeter marker and tighten to provide a visual guide.
Note: The selected centimeter marker (see Fig. 6) will represent the Biopsy Needle protrusion beyond the Cannula (D).

FIG. 7 Insert the assembled Biopsy Needle and Handle (F+G) through the Cannula (D). Carefully rotate the Biopsy Needle and Handle (F+G) clockwise until desired biopsy depth is achieved or until the depth gauge of the Biopsy Needle (F) reaches the Cannula (D) luer end. Then rotate Biopsy Needle and Handle (F+G) counterclockwise and remove. Remove the Handle (G) from the Biopsy Needle (F); insert the Ejector Pin (H) through the Biopsy Needle (F) from the luer end and eject the sample.
Note 1: Repeat process from Fig.6 if desired and anatomically safe.
Note 2: A syringe can be connected to the luer end of the Biopsy Needle (F) and light aspiration may be applied during removal of the Biopsy Needle (F) if desired.
Note 3: In the case of sclerotic lesions, taking several incremental, smaller, samples are recommended to avoid crushing tissue within Biopsy Needle (F).

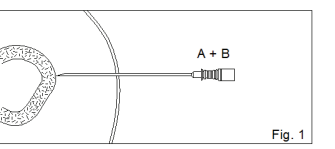


Fig. 1

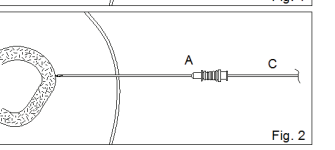


Fig. 2

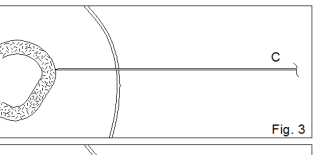


Fig. 3

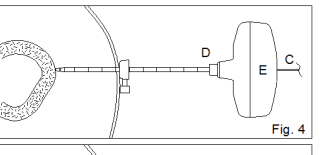


Fig. 4

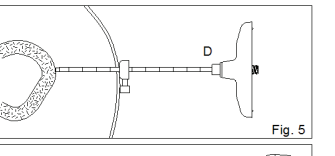


Fig. 5

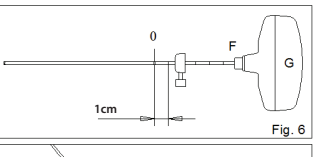


Fig. 6

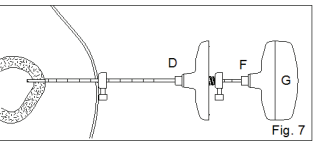


Fig. 7

#1	KBC1110	KBC1115
A	18G x 9cm	18G x 15cm
C	Ø0.9mm x 25cm	Ø0.9mm x 30cm
D	11G x 10cm	11G x 15cm
E	Ø2.3mm x 13.9cm	Ø2.3mm x 18.9cm
F	Ø2.35mm x 20cm	Ø2.35mm x 24cm
H	Ø1.7mm x 23.4cm	Ø1.7mm x 27.4cm

#2	KBC1110	KBC1115
	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.

CE 2797

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
EU Customer Service +31 43 358 82 22

403928001_002 ID 2020-08-18