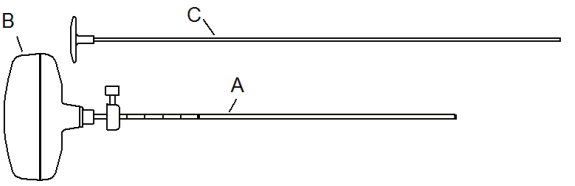
PRESTON™

Bone Biopsy Needle

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The PrestonTM Bone Biopsy Needle is designed for the biopsy of bone lesions. The contents of the system are listed in Table 1. Component working lengths are provided in Table 2. Corresponding Merit Bone Biopsy Systems are given in Table 3.

Table 1: List of components

A	Biopsy Needle
B	Biopsy Handle (with Stiffener)
C	Ejector Pin

Table 2: Component working length

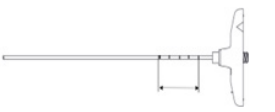
Component	Working length definition:	Working length size and image:
Biopsy Needle	Distal laser mark to the proximal laser mark	 CD1110: 50.5 mm CD1115: 40.5 mm

Table 3: Corresponding Bone Biopsy Systems

CD1110	**CD1115**
KBD1110	**KBD1115**
KBC1110	**KBC1115**
KDPD1110	**KDPD1115**

INTENDED USE
Biopsy of bone lesions.

CONTRAINDICATIONS
Contraindicated for use on patients who are receiving heavy anticoagulant therapy or who have a severe bleeding problem.

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 benefit of the device is reduced morbidity and mortality compared to open surgical procedures.

PERFORMANCE CHARACTERISTICS
- The Preston Biopsy Needle with clockwise-cutting trephine teeth is for use through Merit 11G introducer needles.
- Visual depth gauge and centimetric markings will show protrusion beyond the appropriate 11G, 10cm or 15cm access needle (when using with Merit Bone Biopsy Systems).

STORAGE
Store in a cool, dry place (below 26° C) away from humidity and direct heat. Do not use after expiration 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.
- In the event of a malfunction of the device and/or changes in the performance of the device, exercise caution as this may indicate a change that may affect the safety of the device.
- This device includes stainless-steel alloy components that contain Cobalt (EC No.: 231-158-0; CAS No.: 7440-48-CD1110 CD1115 KBD1110 KBD1115 KBC1110 KBC1115 KDPD1110 KDPD11154) defined as CMR 1B in 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 biopsy of bone. The approach should be accurately planned using diagnostic imaging and clinically approved techniques. The Bone Biopsy Needle should be used in conjunction with the corresponding size Merit bone biopsy systems. See Table #3. In the case of sclerotic lesions, taking several incremental, smaller, samples are recommended to avoid crushing tissue within the Biopsy Needle.

FIG. 1 Adjust the depth gauge on the Biopsy Needle (A) to the appropriate centimeter marker and tighten to provide a visual guide.
Note: The selected 1cm marker (see Fig. 1) will represent the biopsy protrusion beyond access cannula when using with the corresponding size Merit access needle (supplied separately).

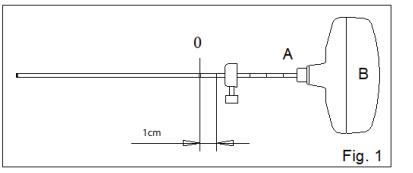


Fig. 1

FIG. 2 Insert the assembled Biopsy Needle and Handle (A+B) through the access cannula.
Carefully rotate the Biopsy Needle (A+B) clockwise until desired biopsy depth is achieved (or until the depth gauge of the Biopsy Needle (A) reaches the access cannula luer end (when using with corresponding size Merit access needles).
Then rotate Biopsy Needle and Handle (A+B) counterclockwise and remove. Remove the Handle (B) from the Biopsy Needle (A); insert the Ejector Pin (C) through the Biopsy Needle (A - from the luer end) and eject the sample.
Note 1: Repeat process from Fig.1 if desired and anatomically safe
Note 2: A syringe can be connected to the luer end of the Biopsy Needle (A) and light aspiration may be applied during removal of the Biopsy Needle (A) if desired.

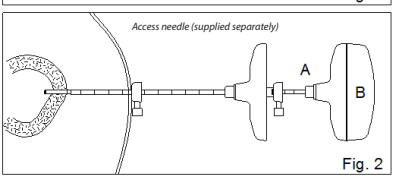


Fig. 2

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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CE 2797

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