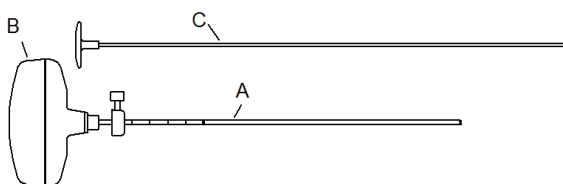


PRESTON™

Bone Biopsy Needle

INSTRUCTIONS FOR USE



CONTENTS

For specific sizes, see included table #1.

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

INDICATIONS FOR USE

Biopsy of bone lesions.

PRECAUTIONS

The device should be used only by or under supervision of a physician trained in biopsy or radiological interventions. Carefully check the contents of the package prior to use and verify that all parts are present and undamaged. Be careful not to bend the components of the device and use manual force only during the procedure. Never use a hammer. When using other tools, first check the compatibility (length and gauge) of these tools with the device components. After use, each component of the device may be a potential biohazard. Handle and dispose such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations. The device must never be re-used even if it appears to be intact. It is a disposable device.

STORAGE

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

REUSE PRECAUTION STATEMENT

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.

CONTRAINDICATIONS

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

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 access needles or bone biopsy systems. See included table #2.

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. 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.

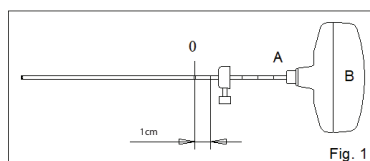


Fig. 1

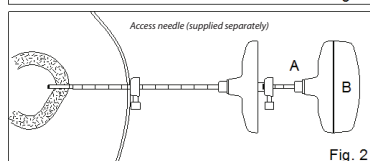









Fig. 2

#1	CD1110	CD1115
A	Ø2.35mm x 20cm	Ø2.35mm x 24cm
C	Ø1.7mm x 23.4cm	Ø1.7mm x 27.4cm

#2	CD1110	CD1115
	KBD1110	KBD1115
	KBC1110	KBC1115
	KDPD1110	KDPD1115
	OM1110	OM1115
	KTP1110	KTP1115
	KBP1110	KBP1115
	ANP1110	ANP1115
	TV1110	

	Single use
	Do not resterilize
	Caution: consult accompanying documents
	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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