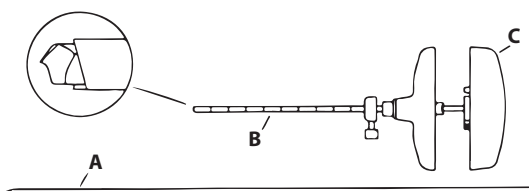


# PRESTON™

## Hard Bone Introducer

### INSTRUCTIONS FOR USE



#### PRODUCT DESCRIPTION

The Preston™ Hard Bone Introducer is designed to traverse hard bone, allowing access for a subsequent bone biopsy procedure (supplied separately). The product has the following contents. For specific sizes, see Table #1.

<b>A</b>	Guide Rod
<b>B</b>	Cutting (Access) Cannula
<b>C</b>	Drill Insert

#### INDICATIONS FOR USE

Traversing hard bone to allow for a subsequent bone biopsy procedure. To be used with Westbrook™ Bone Biopsy System or Kensington™ Guide Wire Bone Biopsy System in corresponding lengths (supplied separately, see Table #2).

#### 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 procedure should be accurately planned and executed using diagnostic imaging and clinically approved techniques. If while following the instructions for use for the Westbrook Bone Biopsy System or Kensington Guide Wire Bone Biopsy System you need to use the Preston Hard Bone Introducer of corresponding length (supplied separately, see Table #2) to pass through hard bone to reach the biopsy site, follow these instructions.

**FIG. 1** With the Stylet removed, insert the Guide Rod (A) through the Blunt Cannula that is already in place, until in contact with the bone.

**FIG. 2** Hold the Guide Rod (A) firmly against the bone and withdraw the Blunt Cannula.

**FIG. 3** Unlock and remove the Drill Insert (C) from the Cutting Cannula (B). Slide the Cutting Cannula (B) down over the Guide Rod (A) until in contact with the skin. Introduce the Cutting Cannula (B) by rotating counterclockwise, until in contact with the bone.

**Note:** To protect soft tissue, a counterclockwise rotation must be applied during Cutting Cannula (B) insertion through the soft tissue.

**FIG. 4** Withdraw the Guide Rod (A) while holding the Cutting Cannula (B) firmly against the bone.

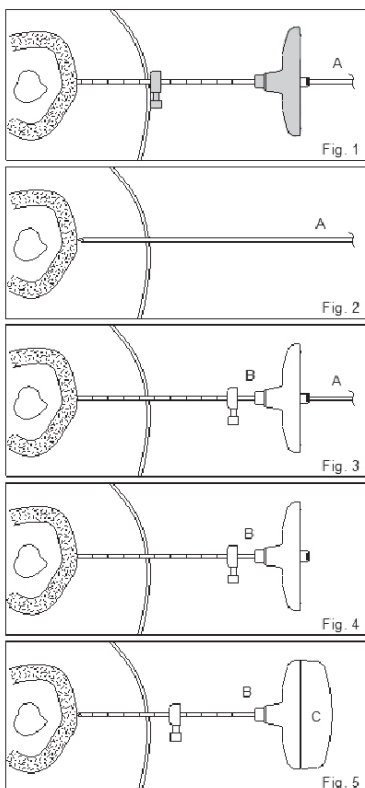
**FIG. 5** Move the depth gauge on the Cutting Cannula (B) forward until in contact with the skin, then adjust it depending on the depth of the lesion for biopsy to the appropriate centimeter marker and tighten to provide a visual guide.

Introduce the Drill Insert (C) into the Cutting Cannula (B) and lock the handles together.

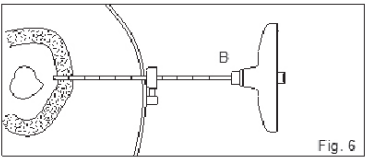
**Note 1:** It may be necessary to withdraw the Cutting Cannula (B) by approximately 2mm in order to lock the handles.

With careful but firm turns, rotate the Cutting Cannula and Drill Insert (B+C) clockwise until the depth gauge reaches the skin and/or desired position is obtained.

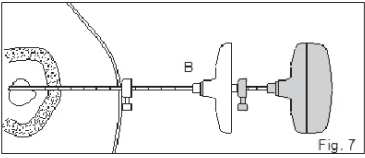
**Note 2:** To maintain penetration efficiency during drilling, it is recommended to remove the Drill Insert (C) from time to time and remove any bone debris from the drill grooves.



**FIG. 6** Firmly hold the Cutting Cannula (B), then unlock and remove the Drill Insert (C).



**FIG. 7** The Cutting Cannula (B) is now in place to perform the biopsy using the Westbrook Bone Biopsy System or Kensington Guide Wire Bone Biopsy System (see Table #2).



#1	KTP1110	KTP1115
A	Ø2.3mm x 25cm	Ø2.3mm x 30cm
B	11G x 10cm	11G x 15cm
C	Ø2.4mm x 13.7cm	Ø2.4mm x 18.7cm

#2	KTP1110	KTP1115
	KBD1110	KBD1115
	KBC1110	KBC1115

	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 <a href="http://www.merit.com/ifu">www.merit.com/ifu</a> and enter IFU ID number. for printed copy, call U.S.A or E.U. Customer Service
	Temperature limitation
<b>Rx ONLY</b>	Federal (USA) law restricts this device to sale by or on the order of a physician.



[www.merit.com](http://www.merit.com)



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