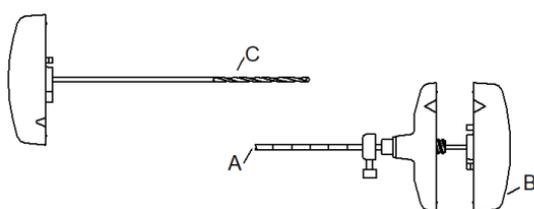


PRESTON™

Hard Bone Access Needle with Drill

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The Preston™ Hard Bone Access Needle with Drill is designed to provide access to bone, including traversing bone when necessary. This access allows for a subsequent bone biopsy procedure (not supplied). The Preston has the following contents. For specific sizes, see Table #1.

A	Cutting (Access) Cannula
B	Stylet with Trocar Tip
C	Drill Insert

INDICATIONS FOR USE

Percutaneous bone access (with the intent to then perform a bone biopsy - not supplied).

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 with other devices, 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 bone being accessed, adjust the depth gauge on the Cutting Cannula (A) to the appropriate centimeter marker and tighten to provide a visual guide. Introduce by rotating counterclockwise the assembled Cutting Cannula and Stylet with Trocar Tip (A+B) until engaged with the bone surface.

Note 1: To protect soft tissue, a counterclockwise rotation must be applied during insertion through the soft tissue.

Note 2: After verifying position and angle, Cannula and Stylet (A+B) may be turned in a clockwise/anticlockwise method with gentle pressure to anchor into bone.

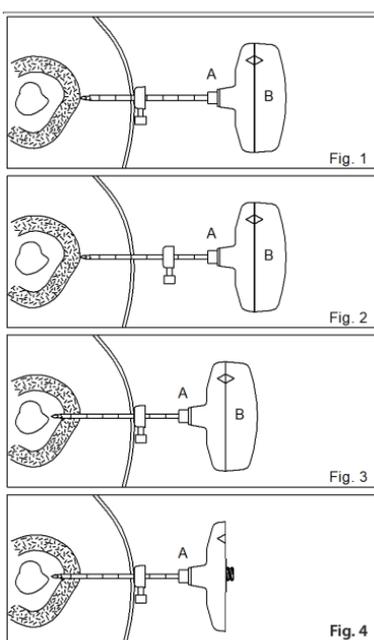
FIG. 2 Depending on the location requiring access within the bone, adjust the depth gauge on the Cutting Cannula (A) forward until in contact with the skin, then withdraw it by the desired depth, using the centimeter markers on the Cutting Cannula (A) to provide a visual guide.

FIG. 3 With careful but firm turns, rotate the Cutting Cannula and Stylet (A+B) clockwise until the depth gauge reaches the skin and/or desired position is obtained.

Note 1: If access is difficult, remove the Stylet (B), insert the Drill (C) in the Cutting Cannula (A) and lock the two parts together to assemble. Restart drilling with clockwise turns. During drilling, to maintain penetration efficiency, it is recommended to remove the Drill (C) from time to time and remove any bone debris from the drill grooves.

FIG. 4 Firmly hold the Cutting Cannula (A) and remove the Stylet (B). The Cutting (Access) Cannula (A) is now in place for biopsy.

Note: A syringe can be connected to the luer end of the Cutting Cannula (A) if desired.



#1	ANP1165	ANP1185	ANP1110	ANP1115
A	11G x 6.5cm	11G x 8.5cm	11G x 10.0cm	11G x 15cm
B	Ø2.4mm x 10.3cm	Ø2.4mm x 12.3cm	Ø2.4mm x 14.0cm	Ø2.4mm x 19.0cm
C	13G x 9.8cm	13G x 11.8cm	13G x 13.7cm	13G x 18.7cm

	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
	Federal (USA) law restricts this device to sale by or on the order of a physician.



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



Authorized Representative:
 Merit Medical Ireland Ltd,
 Parkmore Business Park West,
 Galway, Ireland
 EU Customer Service +31 43 358 8222