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.

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 resterilize. 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.
#1

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- 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.