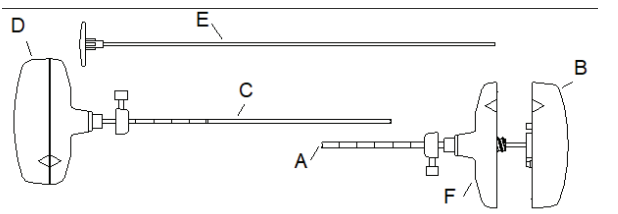
MADISON MINI™

Bone Biopsy System

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION
The Madison Mini™ Bone Biopsy System is designed for accessing bone, traversing bone when necessary, and performing bone biopsies. The system has the following contents.

A	Cutting (Access) Cannula 13G x 6cm	**D**	Biopsy Handle (with stiffener)
B	Stylet with Trocar Tip Ø1.9mm x 10.2cm	**E**	Ejector Pin Ø1.3mm x 17.4cm
C	Biopsy Needle with Clockwise Tip Ø1.85mm x 14cm	**F**	Cannula Handle (Removable)

INDICATIONS FOR USE
Bone access and biopsies of bone lesions.

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 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 to be reached, adjust the depth gauge on the Cutting Cannula (A) to the appropriate centimeter marker and tighten to provide a visual guide. Introduce, rotating counterclockwise, the assembled Cutting Cannula and Stylet and Handle (A+B+F) until engaged with the bone surface.
Note: To protect soft tissue, a counterclockwise rotation must be applied during insertion through the soft tissue.

FIG.2 Move the depth gauge forward until in contact with the skin, then withdraw it by the desired depth, using the centimeter markings on the Cutting Cannula (A) to provide a visual guide.

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

FIG. 3 Firmly hold the Cutting Cannula with Handle (A+F) and unscrew and remove the Stylet (B).
If desired, the Handle (F) can be removed from the Cutting Cannula (A) by placing two fingers under the Handle (F) and pressing the luer end of the Cutting Cannula (A) with the thumb.
Note: To replace the Stylet (B) in the Cutting Cannula (A), place first the Handle (F) on the luer end of the Cutting Cannula (A) by aligning tabs and slots. Then insert the Stylet (B) at a right angle to the assembled Cutting Cannula and Handle (A+F) and screw it until it clicks into place.

FIG. 4 Adjust the depth gauge on the Biopsy Needle (C) to the appropriate centimeter marker and tighten to provide a visual guide.
Note: The selected centimeter marker will represent the Biopsy Needle (C) protrusion beyond Cutting Cannula (A).

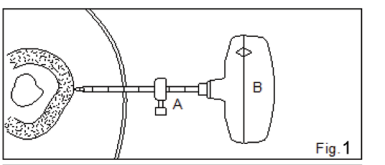


Fig. 1

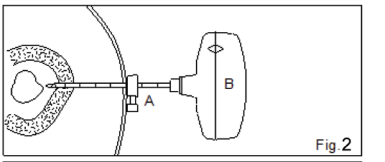


Fig. 2

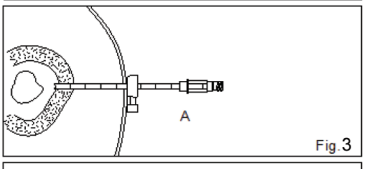


Fig. 3

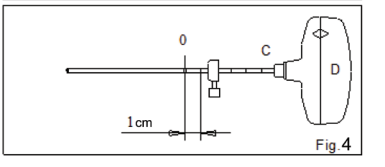


Fig. 4

FIG. 5 Insert the assembled Biopsy Needle and Handle (C+D) through the Cannula (A). Carefully rotate the Biopsy Needle (C+D) clockwise until desired biopsy depth is achieved (or until the depth gauge of the Biopsy Needle (C) reaches the Cannula (A) luer end). Then rotate Biopsy Needle and Handle (C+D) counterclockwise and remove. Remove the Biopsy Handle (D) from the Biopsy Needle (C); insert the Ejector Pin (E) through the Biopsy Needle (C) from the luer end and eject the sample.

Note 1: Repeat process from Fig.4 if desired and anatomically safe.

Note 2: A syringe can be connected to the luer end of the Biopsy Needle (C) and light aspiration may be applied during removal of the Biopsy Needle (C) if desired.

Note 3: In the case of sclerotic lesions, taking several incremental, smaller, samples are recommended to avoid crushing tissue within Biopsy Needle (C).

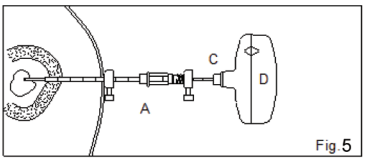


Fig.5

	Single use
	Do not resterilize
	Caution: consult accompanying documents
STERILE EO	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
26°c	Temperature limitation
℞ ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.

CE 2797

www.merit.com

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

EC REP **Authorized Representative:**
Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22

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