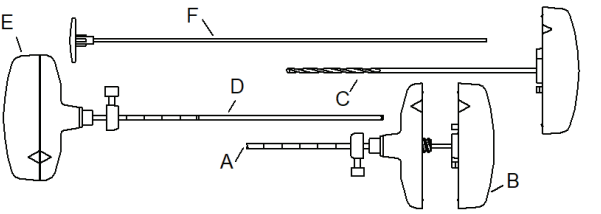
MADISON™

Perforating Bone Biopsy System with Drill

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The Madison™ Perforating Bone Biopsy System with Drill is designed for accessing bone, traversing bone when necessary, and performing bone biopsies. The system has the following contents. For specific sizes, see Table #1.

A	Cutting (Access) Cannula	**D**	Biopsy Needle with Clockwise Tip
B	Stylet with Trocar Tip	**E**	Biopsy Handle (with stiffener)
C	Drill Insert	**F**	Ejector Pin

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 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 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.

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. Firmly hold the Cutting Cannula (A) and remove the Stylet (B).
Note: If the insertion process 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 Adjust the depth gauge on the Biopsy Needle (D) to the appropriate centimeter marker and tighten to provide a visual guide.
Note: The selected centimeter marker (see Fig. 4) will represent the Biopsy Needle protrusion beyond Cutting Cannula (A).

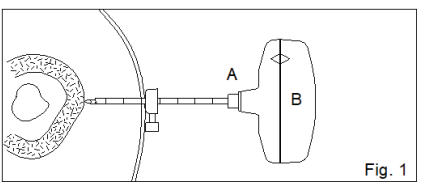


Fig. 1

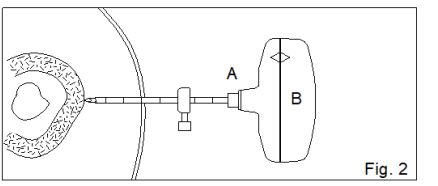


Fig. 2

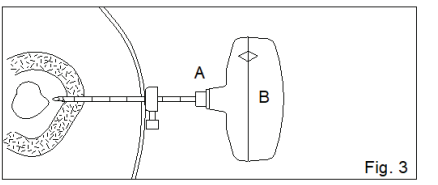


Fig. 3

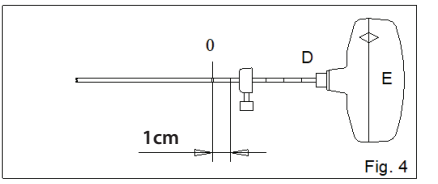


Fig. 4

FIG. 5 Insert the assembled Biopsy Needle and Handle (D+E) through the Cannula (A).
Carefully rotate the Biopsy Needle (D+E) clockwise until desired biopsy depth is achieved (or until the depth gauge of the Biopsy Needle (D) reaches the Cannula (A) luer end.
Then rotate Biopsy Needle and Handle (D+E) counterclockwise and remove. Remove the Handle (E) from the Biopsy Needle (D); insert the Ejector Pin (F) through the Biopsy Needle (D) 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 (D) and light aspiration may be applied during removal of the Biopsy Needle (D) if desired.
Note 3: In the case of sclerotic lesions, taking several incremental, smaller, samples are recommended to avoid crushing tissue within Biopsy Needle (D).

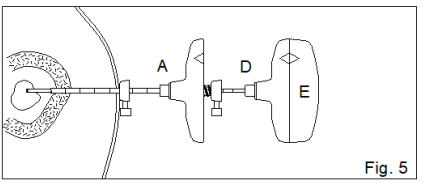


Fig. 5

#1	KDPD1165	KDPD1185	KDPD1110	KDPD1115
A	11G x 6.5cm	11G x 8.5cm	11G x 10.0cm	11G x 15.0 cm
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
D	Ø2.35mm x 16.0cm	Ø2.35mm x 18.0cm	Ø2.35mm x 20cm	Ø2.35mm x 24.0cm
F	Ø1.7mm x 19.3cm	Ø1.7mm x 21.3cm	Ø1.7mm x 23.4cm	Ø1.7mm x 27.4cm

	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.

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CE 2797

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