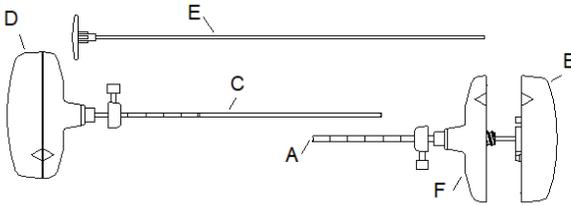


INSTRUCTIONS FOR USE



A	Sharp tip Cannula	D	Handle (with stiffener)
B	Trocar Tip Stylet	E	Ejector pin
C	Biopsy Needle with sharp trephined tip	F	Handle (Inner removable handle)

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. The device is supplied sterile. Check that the sterile package is intact. The device is single use and must not be cleaned and/or sterilized again. The incurred risk is a deterioration of the device and/or a contamination of the patient. 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 finger 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.

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

The Perforating Bone Biopsy Minikit is 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 penetration of the bone. The puncture towards a lesion should be accurately planned using diagnostic imaging. After disinfection, apply local anesthetic using the anesthesia needle.

FIG. 1 Perform anaesthesia with the anesthesia needle all the way down to the periosteum or the lesion itself.

FIG. 2 Make a small skin incision; adjust the depth gauge of the Perforating Cannula Stylet (A+B) and insert while rotating COUNTERCLOCKWISE until bone is reached.

Note: If the anaesthesia needle is left in the correct location, the insertion of the Sharp Tip Cannula and the Stylet (A+B) parallel to it may facilitate the procedure

Note: in order to protect soft tissue, a counterclockwise rotation must be applied during penetration.

FIG. 3 Remove the Anaesthesia needle. After determining the drilling depth, adjust backward the depth gauge on the Sharp Tip Cannula (A). Carefully rotate the Perforating Cannula Stylet (A+B) CLOCKWISE until the depth gauge reaches the skin.

FIG. 4 Unscrew and remove the Stylet (B). The handle (F) may also be removed by placing two fingers under the handle and pressing the Luer End with the thumb.

Note: To place back the Stylet (B) in the Sharp Tip Cannula (A), place first the handle (F) on the Luer Lock end of the Sharp Tip Cannula (A) with respect to the alignment keys and slots. Then insert the Stylet (B) perpendicular to the Sharp Tip Cannula (A) and screw it until it clicks into place.

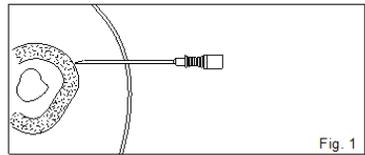


Fig. 1

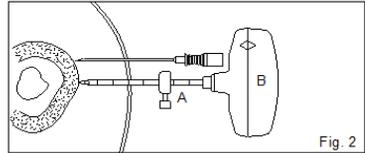


Fig. 2

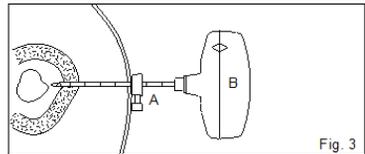


Fig. 3

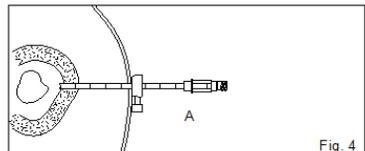


Fig. 4

FIG. 5 Adjust the depth gauge of the Biopsy needle (C) on the indicator wanted (break indicator every 10mm). The selected indicator (see Fig. 4) will represent the protrusion of the biopsy needle (C) beyond the tip of the Sharp Tip Cannula (A).

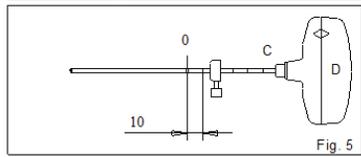


Fig. 5

FIG. 6 Insert the Biopsy needle (C) together with its handle (D) in the Sharp Tip Cannula (A). Carefully rotate the Biopsy needle clockwise until the depth gauge of the Biopsy needle reaches the Sharp Tip Cannula Luer end. Remove counterclockwise the Biopsy needle (C+D); insert the ejector pin (E) in the Biopsy needle and eject the sample out.

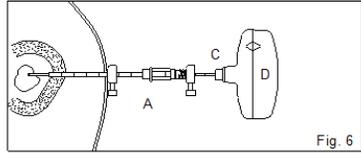


Fig. 6

Note: After removing the plastic handle (D), a syringe can be connected to the Luer end of the Biopsy needle and light aspiration may be applied during removal of the Biopsy needle.

	OM1165	OM1110	OM1115
A	18G x 7cm	18G x 10cm	18G x 15cm
C	Ø1mm x 21cm	Ø1mm x 25cm	Ø1mm x 29.5cm
D	11G x 6.5cm	11G x 10.8cm	11G x 15cm
E	Ø2.4mm x 10cm	Ø2.4mm x 14cm	Ø2.4mm x 19cm
G	Ø2.4mm x 10cm	Ø2.4mm x 14cm	Ø2.4mm x 19cm
H	Ø2.35mm x 16cm	Ø2.35mm x 20cm	Ø2.35mm x 24cm
K	Ø1.7mm x 19.3cm	Ø1.7mm x 23.4cm	Ø1.7mm x 27.4cm

STORAGE

Store in a dry, cool, dark place. Do not use after expiration date.

	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
Rx ONLY	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