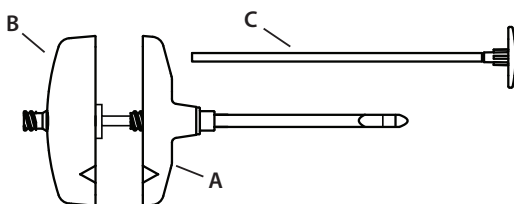


Muscle Biopsy Needle

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The Muscle Biopsy Needle is designed for percutaneous sampling of muscle tissue.

A	Cannula (with Sampling Window)	Ø5mm x 10cm
B	Cutting Mandrel	Ø4mm x 11.7cm
C	Ejector Pin	Ø3.5mm x 14.9cm

INDICATIONS

Biopsies of muscle tissue.

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 and executed using diagnostic imaging and clinically approved techniques. Disinfect the skin and perform anesthesia.

FIG. 1 After making a small skin incision, gently insert the Muscle Biopsy Needle's assembled Cannula and Cutting Mandrel (A+B) to position and orient the Cannula's (A) Sampling Window to the desired biopsy location.

Note: The triangular marker situated on the handle of the Cannula (A) enables you to visualize the orientation of the biopsy window.

FIG. 2 Holding the Cannula (A) in position, withdraw the Cutting Mandrel (B) by approximately 2cm. This will open the Cannula's Sampling Window.

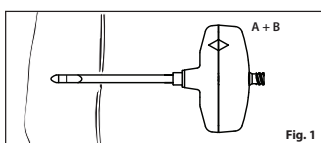


Fig. 1

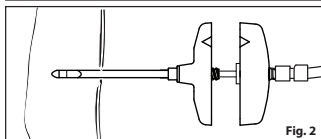
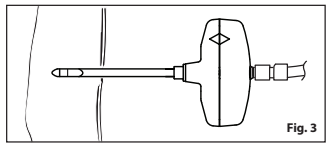


Fig. 2

Connect a 50ml syringe with tube to the luer lock of the Mandrel (B). Draw and hold the syringe plunger to create and maintain a vacuum (to pull muscle tissue into the open Sampling Window).

FIG. 3 While maintaining the position of the Cannula (A), push the Cutting Mandrel (B) to close the Cannula's Sampling Window.



To retrieve sample, remove the Cutting Mandrel (B) with the connected syringe. Release the vacuum and disconnect the syringe and tubing from the Cutting Mandrel (B). Insert the Ejector Pin (C) into the luer end of Cutting Mandrel (B) to eject the sample.

To perform another biopsy, re-insert the Cutting Mandrel (B) into the Cannula (A) already in position. Rotate the Muscle Biopsy Needle's assembled Cannula and Cutting Mandrel (A+B) by 90 degrees to position and orient the Cannula's (A) Sampling Window to the desired biopsy location. Follow directions from Fig. 2 .

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



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