English

CorVocet™

BIOPSY SYSTEM

INSTRUCTIONS FOR USE

DESCRIPTION OF THE PRODUCT
The Merit Corvocet™ Biopsy System is a sterile single patient use device comprised of a core needle biopsy device and optional coaxial introducer. It is available in several needle gauge sizes and lengths. The top and rear actuator buttons on the device are color coded according to the various gauge sizes, Yellow=20 gauge, Pink=18 gauge, Purple=16 gauge and Green=14 gauge.

INDICATIONS FOR USE
The disposable Corvocet Biopsy System is intended for use in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

CONTRAINDICATIONS
Physician judgment is required when considering biopsy on patients with bleeding disorders, or receiving anticoagulant medications.

℞ Only **Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physcian trained and/or experienced in the use of this device.

WARNINGS
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and with applicable local, state, and federal laws and regulations.
- Unusual force applied to the needle or unusual resistance against the needle may cause the needle to deform or bend. A bent or deformed needle may not function properly.
- Post-biopsy care may vary with the biopsy technique utilized and the individual patient's physiological condition. Observation of vital signs and other precautions should be taken to avoid and/or treat potential complications that may be associated with biopsy procedures.
- The collection of multiple needle cores may help to ensure the detection of any cancer tissue. A "negative" biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma.
- The Corvocet Biopsy System is not intended for use in bone.

PRECAUTIONS
- This product should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of core needle biopsy, in particular, those relating to the specific physiology being biopsied.
- 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.
- Inspect the product for damage. If damaged, appropriately discard the entire device and prepare a new instrument.
- These instructions for Corvocet are NOT meant to define or suggest any medical or surgical technique. The individual physician is responsible for the proper procedure and techniques to be used with this product.
- Never test the product by firing into the air. Damage may occur to the device and could result in patient and/or user injury.
- The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT). This product has not been tested for MR imaging compatibility.

NOTE: If collecting multiple samples, inspect the needle for a damaged point, bent shaft or other imperfections after each sample is collected. Do not use the needle if any imperfection is noted.

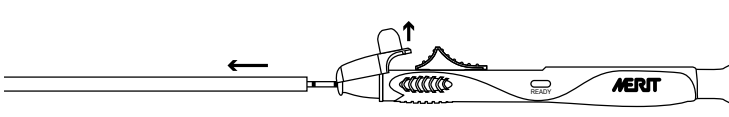
POTENTIAL COMPLICATIONS
Potential complications associated with core biopsy procedures are site specific and include, but are not limited to:

- Air Embolism
- Bleeding
- Unintended Organ Injury
- Track Seeding
- Infection
- Perforation
- Hematoma
- Hemorrage
- Adjacent tissue injury
- Pain
- Hemoptysis
- Hemothorax
- Non-target tissue, organ or vessel perforation
- Pneumothorax

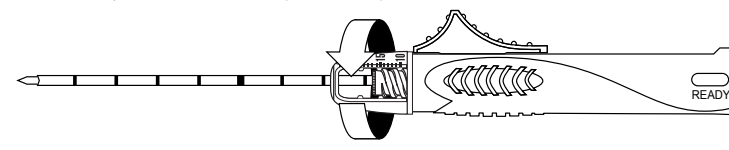
Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

INSTRUCTIONS FOR USE

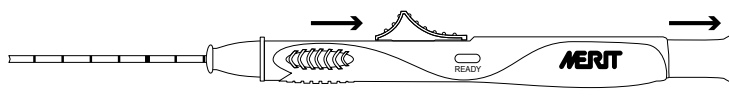
BIOPSY DEVICE PREPARATION
1. Using aseptic technique remove the biopsy device from its package. Remove protective needle sheath that is secured to device and pull back slightly on the top trigger to remove packaging clip.



2. Adjust device throw length to desired level (usable range is 10 mm – 25 mm). Each "click" is 0.5 mm. The colored line on the adjustment dial indicates the penetration depth.

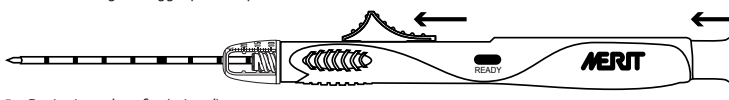


3. Energize (prime) device by pulling back on the top or rear trigger until you feel a click. When the device is primed, a yellow indicator will show in the indicator window (labeled "ready").



4. Advance the rear or top trigger until you feel a slight increase in resistance.

NOTE: Advancing the trigger past this point of increased resistance will cause the device to fire.

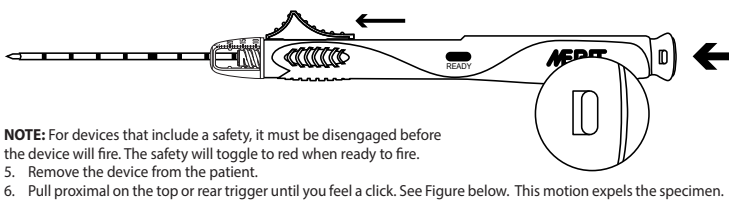


5. Device is ready to fire (primed).

BIOPSY PROCEDURE (WITHOUT OPTIONAL COAXIAL INTRODUCER)
1. Using aseptic technique, prepare site as required. Adequate anesthesia should be considered prior to procedure.
2. Verify instrument is ready to fire (primed).
3. Advance the needle tip of the biopsy device to a position proximal to the desired biopsy site.

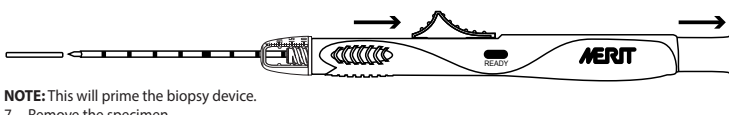
NOTE: Once fired, the biopsy needle will travel to the preset penetration depth beyond the biopsy needle tip.

4. While maintaining the device's position and needle orientation, depress the rear trigger or push the top trigger distally to cause the needle to automatically advance.



NOTE: For devices that include a safety, it must be disengaged before the device will fire. The safety will toggle to red when ready to fire.

5. Remove the device from the patient.
6. Pull proximal on the top or rear trigger until you feel a click. See Figure below. This motion expels the specimen.



NOTE: This will prime the biopsy device.

7. Remove the specimen.
8. If additional biopsies are required, advance the rear or top trigger until you feel a slight increase in resistance.

NOTE: Advancing the triggers past this point of increased resistance will cause the device to fire.

9. Device is ready to fire (primed). Repeat steps 2-8 for all additional biopsies.

NOTE: If collecting multiple samples, inspect the needle for damaged point, bent shaft or other imperfections after each sample is collected. Do not use needle if any imperfection is noted.

10. After your last sample is collected it is recommended that you disengage the device by dry firing it before you discard it.

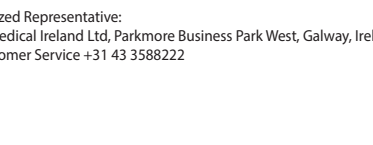
BIOPSY PROCEDURE (WITH OPTIONAL CORVOCET COAXIAL INTRODUCER)
Select the appropriate Corvocet Coaxial Introducer to correspond with the gauge and length of the Corvocet Biopsy System in use. Refer to catalog for product numbers and descriptions.

NOTE: An optional blunt tip stylet may be included with 18 and 20 gauge Corvocet Biopsy Systems. The blunt tip stylet may be used to manipulate through soft tissue and around vasculature or other organs to minimize the risk of unintentional damage to these areas.

1. Using aseptic technique, prepare site as required. Adequate anesthesia should be considered prior to procedure.
2. Using aseptic technique, remove the Corvocet Coaxial Introducer from its package.
3. If preferred, advance the supplied depth stop to the predetermined placement depth.

NOTE: The depth stop should be adjusted so that the coaxial introducer is in proper position when the depth stop is in contact with the skin. This will help stabilize the Corvocet Coaxial Introducer.

4. Using image guidance, insert the tip of the Corvocet Coaxial Introducer proximal to the lesion to be biopsied using the depth stop as an aid for proper placement and adjust as necessary.
5. Hold the guiding cannula needle hub. Squeeze the stylet hub and pull proximally to remove the stylet from the outer cannula. Leave the cannula in place as a guide for the placement of the Corvocet biopsy device.



6. Verify instrument is ready to fire (primed).
7. Place the Corvocet biopsy device all the way through the guiding cannula to the lesion to be biopsied.

NOTE: There should not be a gap between the hub of the Corvocet Coaxial Introducer and the proximal end of the biopsy device.

8. Ensure device needle tip is at the correct location.

NOTE: Once fired the biopsy needle will travel to the preset penetration depth beyond the biopsy needle tip.

9. While maintaining the device's position and needle orientation, depress the rear trigger or push the top trigger distally to cause the needle to automatically advance.

NOTE: For devices that include a safety it must be disengaged before the device will fire.

10. Remove the device from the patient.
11. Pull proximal on the top or rear trigger until you feel a click. This motion expels the sample.

NOTE: This will prime the biopsy device.

12. Remove the specimen.
13. If additional biopsies are required, advance the rear or top trigger until you feel a slight increase in resistance.

NOTE: Advancing the triggers past this point of increased resistance will cause the device to fire.

14. Device is ready to fire (primed). Repeat steps 6-12 for all additional biopsies.

NOTE: If collecting multiple samples, inspect the needle for damaged point, bent shaft or other imperfections after each sample is collected. Do not use needle if any imperfection is noted.

15. After your last sample is collected it is recommended that you disengage the device by dry firing it before you discard it.

Recommendation: When collecting multiple samples, wipe the core tissue biopsy needle with sterile moist gauze prior to reinsertion into the guiding cannula. This will aid in proper movement of the Corvocet biopsy needle within the cannula.

⚠	Caution: Consult accompanying documents
②	Single use only
	Do not use if package is damaged
REF	Catalog Number

LOT	Lot Number
	Use By
STERILE EO	Sterilized Using Ethylene Oxide

MERIT MEDICAL®

CE 0086

Manufacturer:
Merit Medical Systems, Inc. 1600 West Merit Parkway, South Jordan, Utah 84095
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