BIOPSY PROCEDURE (WITH OPTIONAL CORVOCET COAXIAL INTRODUCER)

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. Remove protective needle sheath that is secured to device and pull back slightly on the top trigger to remove packaging clip. There should not be a gap between the hub of the Corvocet Coaxial Introducer and the distal end of the outer cannula. Leave the cannula in place as a guide for the placement of the Corvocet biopsy device.

3. Energize (prime) device by pulling back on the top or rear trigger until you feel a click. When the device is primed, the safety will toggle to red when ready to fire. For devices that include a safety, it must be disengaged before the device will fire. The collection of multiple needle cores may help to ensure the detection of any cancer tissue. A "negative" biopsy may be associated with biopsy procedures.

4. Device is ready to fire (primed).

5. Hold the guiding cannula needle hub. Squeeze the stylet hub and pull proximally to remove the stylet from the outer cannula. The depth stop should be adjusted so that the coaxial introducer is in proper position when the depth stop is engaged to keep the biopsy needle within the core tissue. 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. Remove the specimen.

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

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

10. After your last sample is collected it is recommended that you disengage the device by dry firing it before you discard it. This will aid in proper movement of the Corvocet biopsy needle within the proximal end of the biopsy device.

NOTE:
- Infection
- Air Embolism
- Hemorrhage
- Hematoma
- Pneumothorax
- Hemoptysis

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

- Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of specific physiology being biopsied.

- The Merit Corvocet™ Biopsy System is a sterile single patient use device comprised of a core needle biopsy device and the proximal end of the biopsy device.

- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may result in severe injury or death.

- 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 collection of multiple needle cores may help to ensure the detection of any cancer tissue. A "negative" biopsy may be associated with biopsy procedures.

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

- If damaged, appropriately discard the entire device and prepare a new device.

- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may result in severe injury or death.

- The device outer cannula is designed for use with the specific gauge stylet. The depth stop is a safety mechanism to prevent unintentional damage to these areas.

- In the presence of suspicious radiographic findings does not preclude the presence of carcinoma.

- Product disengagement before the device will fire.

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