

**INSTRUCTIONS FOR USE**

**DESCRIPTION OF THE PRODUCT**

The Merit Corvocet Coaxial Introducer is a three-part disposable device consisting of an outer (guiding) cannula with an attached female Luer lock hub, an inner stylet with an attached hub, and a flexible slip ring-style depth stop. The Corvocet Coaxial Introducer is designed for use with the Corvocet Biopsy System. The depth stop is color coded to match the gauge size of the appropriate Corvocet Biopsy System., e.g. Yellow = 20 gauge, Pink = 18 gauge, Purple = 16 gauge, Green = 14 gauge.

**INDICATIONS FOR USE**

The Corvocet Coaxial Introducer is intended for use as a guiding needle in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors.

**CONTRAINDICATIONS**

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

**Rx Only Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician 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 core biopsy samples 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.

**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 the 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.
- The introduction of the Corvocet Coaxial Introducer into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.). This product has not been tested for MR imaging compatibility.

**POTENTIAL COMPLICATIONS**

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

- Air Embolism
- Track Seeding
- Bleeding
- Infection
- Unintended Organ Injury
- Perforation

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.

**EQUIPMENT REQUIRED**

The Corvocet Coaxial Introducer is designed for use with Corvocet core needle device. Refer to applicable Instructions for Use.

**INSTRUCTIONS FOR USE**

**NEEDLE PREPARATION**

1. Prior to use, determine the appropriate gauge and length of the needle required for the specific biopsy to be performed. Select the corresponding Coaxial Introducer (Refer to catalog for product numbers and descriptions.)
2. Using aseptic technique, remove the Corvocet Coaxial Introducer from the package and from the protective sheath.



**NOTE:** An optional blunt tip stylet is included with all 18 and 20 gauge Corvocet Biopsy System. 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.

**BIOPSY PROCEDURE**

1. Using aseptic techniques, prepare site as required. Adequate anesthesia should be considered prior to procedure.
2. If preferred, advance the supplied depth stop to the predetermined placement depth.



3. 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.

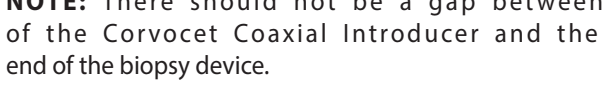
**NOTE:** The depth stop should be adjusted so that the needle is in proper position when the depth stop is in contact with the skin. This will help stabilize the Corvocet Coaxial Introducer.

4. 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 core needle device.



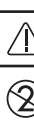






5. Place the appropriate Corvocet core needle device all the way through the guiding cannula to the lesion to be biopsied.

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



6. Perform the biopsy and remove the biopsy device from the guiding cannula. Leave the guiding cannula in place.
7. For multiple samples, reinsert the device and reposition the Corvocet Coaxial Introducer using imaging guidance.

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
	Single use only
	Do not use if package is damaged
	Catalog Number
	Lot Number
	Use By
	Sterilized Using Ethylene Oxide