**DESCRIPTION OF THE PRODUCT**

Consisting of a coaxial introducer needle consisting of an outer (guiding) cannula with an attached female Luer lock hub, a stylet, and a stylet depth stop. The Corvocet Coaxial Introducer is designed for use with Corvocet core needle devices. The guiding cannula is color-coded with the corresponding Coaxial Introducer (Refer to catalog for product numbers and descriptions.)

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.

Air embolism is a rare but serious potential complication of lung biopsy procedures. Procedure details may differ slightly from those described in this section. The instructions for the Corvocet are NOT meant to define or suggest any medical or surgical technique. The individual physician or operator must know the details of the individual procedure and be familiar with the indications, contraindications, limitations, typical procedures and findings, and post-treatment care required. Consultation with a radiologist or surgeon may be necessary prior to placement.

**PRECAUTIONS**

- Use only with the Corvocet Biopsy System.
- The introduction of the Corvocet Coaxial Introducer into the body cavities is limited to a minimum of 6 inches (15 cm).
- The depth of the stylet stop should be adjusted in accordance with the intended application.
- Perform the biopsy and remove the biopsy device from the guiding cannula.
- The depth stop is color coded to distinguish the depth stop from the stylet when withdrawing the device from the body. The depth stop is placed in the guiding cannula by applying a gentle pulling motion to the stylet when withdrawing the device from the body. The depth stop should be visible end of the biopsy device.
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**INDICATIONS FOR USE**

- The Corvocet coaxial introducer is used for 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**

- Air embolism should be considered in any patient with a known or suspected history of heart or lung disease, any patient with the presence of a pacemaker or other electrical device, and in the presence of a sternal or diaphragmatic defect.

**POTENTIAL COMPLICATIONS**

- Complications include, but are not limited to:
  - Infection
  - Symptomatic air embolism
  - Aspiration
  - Unintended organ injury
  - Hemorrhage
  - Inability to withdraw device
  - Hematoma
  - Unusual resistance against the stylet
  - Deformed needle may not function properly.

**EQUIPMENT REQUIRED**

- The Corvocet coaxial introducer
- The Corvocet biopsy device
- Sterile technique
- Aseptic technique
- Appropriate biopsy length
- Appropriate stylet
- Appropriately sized depth stop
- Appropriately sized guiding cannula
- Appropriate biopsy needle
- Sterile technique
- Aseptic technique
- Appropriate biopsy length
- Appropriate stylet
- Appropriately sized depth stop
- Appropriately sized guiding cannula
- Appropriate biopsy needle

**INSTRUCTIONS FOR USE**

**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. Hold the guiding cannula needle hub. Squeeze the stylet hub and pull back to release the stylet. The stylet is connected to the stylet hub and the proximal end of the guiding cannula. Leave the guiding cannula in place.
4. Hold the guiding cannula needle hub. Squeeze the stylet hub and pull back to release the stylet. The stylet is connected to the stylet hub and the proximal end of the guiding cannula. Leave the guiding cannula in place.
5. Place the appropriate Corvocet core needle device all the way through the guiding cannula to the lesion to be biopsied.
6. Perform the biopsy and remove the biopsy device from the guiding cannula.
7. After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and with the use of the accompanying documents.
8. For single patient use only. Do not reuse, reprocess or resterilize. This product should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical procedures and findings, and post-treatment care required. Consultation with a radiologist or surgeon may be necessary prior to placement.

**RECOMMENDATIONS**

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- Appropriate stylet
- Appropriately sized depth stop
- Appropriately sized guiding cannula
- Appropriate biopsy needle

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