

PRESCRIPTIVE INFORMATION

INDICATIONS for USE: The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, breast, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

CONTRAINDICATIONS: Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have bleeding disorders.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

WARNINGS

- Post-biopsy patient 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 finding does not preclude the presence of carcinoma.
- The MONOPTY® Disposable Core Biopsy Instrument is not intended for use in bone.

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.

Note: After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and applicable laws and regulations.

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 organ being biopsied.
- The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.).
- Never test the product by firing into the air. Damage may occur to the needle/cannula tip.
- Unusual force applied to the stylet or unusual resistance against the stylet while extended out of the supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with the needle function.

POTENTIAL COMPLICATIONS:

Potential complications of core biopsy are site specific and may consist of hematoma, hemorrhage, infection, adjacent tissue injury, and pain.

For the latest information, always check the "Instructions for Use" that comes packaged with the product.

This site is intended for healthcare professionals. If you are a patient seeking more information, please consult your healthcare provider.