

PRESCRIPTIVE INFORMATION

INDICATIONS for USE:

The MAGNUM® biopsy system (instrument and needles) is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue tumors.

CONTRAINDICATIONS: Not intended for use in bone.

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

WARNINGS

- Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding disorder.
- 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.
- 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.
- MAGNUM® needles are for single patient use only. Do not reuse. Do not resterilize.

PRECAUTIONS

- Use only BARD® MAGNUM® biopsy needles with the BARD® MAGNUM® biopsy instrument. We cannot recommend the use of biopsy needles made by other manufacturers.
- 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 instrument while the needle is installed in the instrument. This could result in needle damage and/or patient injury.
- Before using, inspect the needle components for damage. **DO NOT USE** if the needle components are damaged. Note: The tip is made with a slight back bend. This is not a defect.
- 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 needle function.
- Inspect the instrument for signs of deterioration or damage (cracking, blistering, separation of coating, pitting). **DO NOT USE** if deterioration or damage is observed.
- After use, the MAGNUM® needles may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local laws and regulations.