IZI Medical

Instruction for Use

Quick-Core Auto - Automatic Programmable Biopsy System

Indication for Use

Quick Core Auto biopsy system is intended for soft tissue biopsy. The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for soft tissue biopsy should be employed.

Caution: Federal (USA) law restricts this device to sale by or on the order a physician. Usage allowed only to qualified physicians.

IMPORTANT:

The procedure described is for guidance only: the use of the device must be based on the clinical training of each physician. **Failure to properly follow the instructions may result in serious patient injury. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.**

Precautions

- Read the Instruction for Use prior to device operation.
- For single patient use only.
- Product may present a biohazard and sharps hazard. Dispose of in accordance with applicable laws and regulations
- **When used for breast biopsy, the product is for diagnosis only**.
- The Quick Core Auto is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of the histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.
- Before using, inspect the needle to exclude the presence of damaged tip, bending or other imperfections that would prevent proper function. If the needle components are damaged or bent, do not use device.
- Unusual resistance against the mandrel during the biopsy maneuver may cause the mandrel to bend at the specimen notch. A bent specimen notch may interfere with the needle function.
- Sterile Device: The device is sterilized by ethylene oxide and not to be resterilized or reconditioned in any way.
- Single-use/single -patient device: reuse of the device may cause cross infection to patient and/or user.
- Verify the integrity of the packaging and the validity of the product before use.
- The product must not be used if the package is unsealed, damaged or wet.
- Keep in a fresh and dry place, avoid the exposure to light and high temperature.
- Do not use in magnetic resonance (MR) environment.

Warning: If device is tested by firing into the air, damage may occur to the sharpening of the cannula and/or the mandrel tip. Do not keep fingers or other objects in front of the device as the needle will advance 2.5cm rapidly, during activation.

Preliminary Activity:

- Using appropriate aseptic technique, remove the device from its package and prepare the biopsy site.
- Disinfect the area of skin and proceed with administering an adequate level of anesthetic.
- If necessary, use a scalpel to make a localized incision into the skin area, to facilitate access of the needle cannula.

Step 1: Preparation of Quick Core Auto biopsy system

Load the Quick Core Auto biopsy system by pulling back the loading levers to the end of the stroke and release twice; the first time to load the cutting cannula, the second time to load the mandrel.

Step 2: Positioning of the Needle

Position the needle tip at or near the lesion to be biopsied. It is recommended to use image guidance systems to reach the desired area.

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Step 3: Fire the Biopsy System
Two firing sequence methods are available once the biopsy system is loaded

1. Delayed Mode (semiautomatic method) – By pressing the D button, the mandrel will trip and advance in the sampling area. The operator will use this delay firing method to verify the position of the biopsy notch in the target area prior to pressing the A button.
   Pressing button A activates the cannula that advances, cutting and capturing the specimen in the biopsy notch.
2. Automatic mode – The operator can choose to use the fully automatic method, by simply pressing button A first. In this way the mandrel and cannula will advance automatically in sequence for the collection and capture of the specimen into the biopsy notch.

   A = Automatic Mode
   D = Delayed Mode (Mandrel only)

Step 4: Biopsy Specimen
To retrieve the collected tissue sample, hold the device with the A and D firing buttons facing up and pull back and release completely the loading levers once. This action will retract the cannula exposing the mandrel biopsy notch containing the specimen.

Step 5: Multiple Sampling
After the tissue sample is removed from the biopsy notch, additional tissue samples from the same patient may be obtained.
Pull back the loading levers a second time to retract the mandrel within the cannula and to make the device ready for use again. Repeat steps 3 to 5.
In the automatic mode, the Quick Core Auto biopsy system is designed to fire mandrel and canula in rapid succession.

Please exercise caution before proceeding as the device will advance 2.5 cm at the time of activation.

Biopsy Procedure with Coaxial Introducer Needle:
The coaxial introductory needle must be used when multiple biopsies of soft tissue are required. Used with Quick Core Auto biopsy system allows multiple accesses to the biopsy site with a single puncture causing less trauma to the patient.

1. Slowly insert the coaxial introducer needle into the tissue up to reach the proximity of the biopsy area.
2. Remove mandrel by turning the handle counterclockwise.
3. Insert the previously charged Quick Core Auto biopsy system inside the coaxial cannula and proceed to the sample collection (refer to the biopsy system instruction for use described in the previous section).
4. Remove Quick Core Auto biopsy system and insert it again to preform multiple biopsies.
5. At the end of procedure, remove all devices and accessories paying attention to the necessary precautions for potentially contaminated materials.
6. Throw away after the use and discharge together with the hospital waste following the laws in force.

Storage
Store in a cool, dry place. Proper care should be taken to ensure that the product will not be damaged or rendered non-sterile.

Limitation of Liability
IN NO EVENT SHALL IZI MEDICAL BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE PRODUCT, BASED UPON BREACH OF CONTRACT (INCLUDING BREACH OF WARRANTY).

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