

Curlew Endoscopic Multibiopsy

US Patents 5,782,747; 5,980,468; 6,071,248; foreign patents and pending

Multibiopsy 9F with Metal Storage Cylinder Hot or Cold 7, 14, or 25 Specimen With in Situ Processing, Individual or Batch Specimen Collection Instructions for Single Use Only

Read this document in its entirety prior to use

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician

Caution: A thorough understanding of the technical principles, clinical application and risks associated with multibiopsy is necessary before using this instrument

Overview

- Multibiopsy orients, serially collects and stores 2.0 mm diameter specimens in a removable perforated metal tip for fixation. In pathology the perforated storage cylinder and last specimen held between the jaws are processed by standard paraffin methods and microtomed in situ. The specimens appear on the microscope slide with the first specimen on the left adjacent to the label in the order of acquisition as documented in the Curlew Endoscopy Log submitted by the endoscopist

Inspection:

- Inspect the package containing the Curlew Multibiopsy. If any damage is noticed, do not use the instrument as sterility may be compromised.
- Open the pouch and remove the instrument. Visually inspect for kinks, bends, breaks or fraying and inspect the handle to insure there are no broken parts. **Do not open and close the jaws without straightening the shaft** as that may alter the precise automated biopsy action. Straighten the shaft and then extend the biopsy jaws by gently pulling back on the thumb loop and retract by advancing the thumb loop to the stop to confirm easy biopsy action. **Note the short 3 mm movement necessary to advance and retract the sharp jaws. Observe that the jaws retract fully into the biopsy storage cylinder** when the thumb loop is advanced to the handle stop.
- **Total jaw retraction automatically captures, orients and stores the specimens in the perforated metal storage cylinder. This action: 1. protects staff from sharps during multibiopsy use; 2. prevents endoscope instrument channel damaged during passage or withdrawal; 3. retains specimens in the storage cylinder during withdrawal from the endoscope, transportation and processing in pathology.**
- **Do not use the Curlew Multibiopsy if any abnormality is found or the instrument is not operating properly. See warranty.**

Multibiopsy Operation in the Endoscopy Suite:

Preparation

- Curlew Multibiopsy 9F requires a minimum 3.2 mm channel.
- Curlew Multibiopsy 9F metal storage cylinder supports standard paraffin processing.
- Prepare the enclosed Curlew Multibiopsy Endoscopy Log (also available from www.curlewendoscopy.com) to record the sequence and site of biopsies.

Passing the Multibiopsy

- Fully retract the jaws into the biopsy instrument shaft by advancing the thumb loop to the stop.

- Pass the **Multibiopsy** through the endoscope instrument port. **With the endoscope bending section straightened, advance the multibiopsy into view. Thereafter the endoscope may be fully deflected.**
- Place the instrument tip close to the desired biopsy site and **gently** retract the thumb loop to extend the sharp jaws.
- Advance the jaws into the biopsy site by either pushing the multibiopsy or advancing the endoscope until the **jaws are firmly pressed into the biopsy site.**
- **Close the jaws by gently advancing the thumb loop to the stop while maintaining pressure on the biopsy site.**
- Move the jaws away from and inspect the biopsy site by either moving the endoscope or the multibiopsy. An elliptical mucosal defect and bleeding site indicate successful biopsy acquisition.
- **Specimen storage in the Curlew Multibiopsy is automatic.** Note the biopsy site and sequence number on the Multibiopsy Endoscopy Log.
- For the **Curlew Multibiopsy 7, 14 or 25** the last specimen is held between the jaws in the metal storage cylinder. This specimen will be processed in situ and will appear on the stained slide separated slightly from the other specimens.
- **Then retract the jaws completely into the metal cylinder by pushing the thumb ring to the handle stop to protect the endoscope instrument channel and hold the specimens in the storage cylinder for removal and during handling in the pathology laboratory. This protects staff from potentially infectious specimens, sharps and patient contaminants.**
- **Straighten the endoscope bending section and remove the Curlew Multibiopsy.**

For Hot Biopsy

- Connect the active cord and place the ground plate on the patient. After closing the jaws to grasp the selected hot biopsy site as described above, pull the multibiopsy away from the gut wall to tent the mucosa and form a neck between the gut wall and the multibiopsy tip. The metal hot multibiopsy should **only** contact the desired hot biopsy site. **Do not fully close the biopsy jaws as that may cut through the biopsy before cautery application.** Apply cautery using power settings appropriate for the electrosurgical unit. When the lesion is cauterized, close jaws to free the biopsy from the tented mucosa by advancing the thumb loop to the handle stop. This automatically cuts and stores the specimen in the storage cassette. The multibiopsy is now ready for the next hot or cold biopsy. Record the site and specimen number in the log.

Preferred Method for Safe and Efficient Use of Curlew Multibiopsy

Complete the diagnostic endoscopy to the distal point. Then insert the appropriate 7, 14 or 25 specimen instrument to perform the biopsies during withdrawal. The endoscope is removed with the multibiopsy in place for transport to the contaminated laboratory. There remove the multibiopsy from the endoscope, separate the storage cylinder and place in a fixative vial with the Curlew label for transport to pathology with the labeled log. This method minimizes contamination of the endoscopy suite and protects staff from infectious specimens, sharps and patient contaminants.

Collection and Fixation of Individual or Batched Multibiopsy Specimens

- **Collection of individual Specimens** Each biopsy specimen is held within the biopsy jaws until retracted into the storage cylinder. The second specimen pushes the preceding specimen into the storage cylinder until the storage area is filled. Individual specimens may be removed from the sharp biopsy jaws by removing the multibiopsy from the endoscope and placing the specimen in fixative. Wash and reuse **only** on the same patient.
- **Collection of Specimen Batches** Specimens batches may be removed by retrieving the multibiopsy and irrigating the collected specimen batch from the storage cylinder into fixative. Retract the thumb ring to open the jaws and irrigate into fixative. Place a blunt 22G tip needle on a 3ml syringe in the proximal slot of the storage cylinder and irrigate into fixative. Wash and reuse **only** on the same patient.

Fixation In Situ of Multibiopsy Specimens in the Perforated Storage Cylinder

- After separating the biopsy instrument from the endoscope **maintain the jaws closed inside the storage cylinder by pressing the thumb ring against the stop. This prevents specimen loss and protects staff.**
- **Cut the black shaft and cable close to the storage cylinder** with a heavy wire cutter, **place the storage cylinder in a Curlew labeled fixative vial** and send to pathology with the labeled log. **Do not cut or damage the cylinder** as this may prevent specimen removal.
- Dispose of the biopsy instrument shaft in accordance with accepted medical practice and applicable local, state and federal laws and regulations for a potential biohazard.

Pathology Processing of Specimens In Situ within the Perforated Storage Cylinder:

- The perforated storage cylinder allows processing of the specimens in situ with a minimum of handling and exposure of staff to human tissue, fluids and solvents.
- The attached black stub of the Curlew multibiopsy shaft closes the biopsy jaws inside the cylinder to hold the specimens in place for processing. Cylinder perforations allow solvent penetration to fix the specimens in situ and during processing.
- Place the entire separated storage cylinder in the processing system for fixation and paraffin impregnation.
- Using appropriate protection, warm the metal cylinder to soften the paraffin. **Do not overheat as melting the paraffin will disrupt the oriented specimen core and acquisition order.** Place a 22G blunt needle in the proximal housing slot. Push the biopsy mechanism distally away from the shaft stub, grasp the exposed sharp jaws and remove the biopsy mechanism surrounding the embedded specimen core. Place the biopsy mechanism and core on lens paper with the jaws holding the last specimen to the right. Spread the jaws and place the paraffin core with the last biopsy specimen held between the jaws to the right on the lens paper. Mark the paper adjacent to the last specimen to indicate the last biopsy and the specimen order within the cassette. Mount the wrap and cut the paper encased specimens. Mount on slides and stain. The paper wrap maintains the specimen order during exposure to hot paraffin for block mounting.
- The last slightly separated specimen adjacent to the mark is placed to the right side of the slide away from the label. **The mark indicates the last biopsy and order of specimen acquisition for mounting on the microtome and slide.** The multibiopsy specimen on the left adjacent to the label is "Biopsy 1" as documented on the Curlew Multibiopsy Log submitted by the endoscopist. The specimens appear on the slide in the order of acquisition from left to right.
- Dispose of the stub shaft, external metal cassette and biopsy mechanism in accordance with accepted medical practice and applicable local, state and federal laws and regulations for a potential biohazard.

Disposal:

- **WARNING:** After use, this product and its parts may be a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Storage:

- Store sterile instruments at room temperature. Do not expose to solvents, radiation, UV light or any other substance that could compromise the sterility of the unit.

Warranty:

- Curlew warrants that the instrument will be free from defects and workmanship for use in a single procedure. This warranty does not apply to the use beyond the expiration date. This device is not intended to be reprocessed. The user assumes responsibility for any consequences related to the use of reprocessed instruments. Curlew obligations under this warranty are limited to the replacement of the instrument.

Revised 9/2010