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 and Cold or Cold 7, 13, or 25 Specimen

with in Situ Paraffin Processing, Single or Batch Specimen Collection

Endoscopy 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 serially collects, orients and stores 2.0 mm diameter biopsies in a removable perforated metal storage cylinder for in situ fixation and paraffin processing with minimum handling and staff exposure to human material, sharps and solvents.
- The Curlew label on the fixative vial indicates the number of specimens. The Curlew log completed by the endoscopist identifies the number of specimens, each specimen biopsy site, the order of acquisition and indication to the pathologist. The specimens appear as serial sections on the microscope slide in acquisition order with the first specimen on the left adjacent to the label.

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. Straighten the shaft and then extend the biopsy jaws by gently pulling back on the thumb ring and retract by advancing the thumb ring 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 ring is advanced to the handle stop.
- Jaw retraction into the storage cylinder captures, orients and stores the specimens in the storage cylinder. This action: (1) retains specimens in the storage cylinder during and after withdrawal from the endoscope, transportation and processing in pathology; (2) protects staff during multibiopsy use; (3) prevents endoscope instrument channel damaged during passage and withdrawal.
- 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

- Complete the diagnostic endoscopy to the distal point. Select the appropriate 7, 13, or 25 specimen cold or hot and cold Curlew Multibiopsy.
- Fully retract the jaws into the biopsy instrument shaft by advancing the thumb ring 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.

For Cold Biopsy

- Place the multibiopsy tip close to the desired biopsy site and gently retract the thumb ring to extend the sharp jaws.
- Advance the jaws into the biopsy site until the jaws are firmly pressed into the biopsy site.
- Close the jaws by gently advancing the thumb ring to the stop while maintaining pressure on the biopsy site.
- This retracts the jaws and specimen into the storage cylinder.
- Move the multibiopsy and inspect the biopsy site. A bleeding mucosal site indicates successful biopsy acquisition.
- Specimen storage is automatic. Note the biopsy site and sequence on the log.
- Repeat until the desired number of biopsies is obtained.
- Then retract the jaws completely into the metal cylinder by pushing the thumb ring to the handle stop to close the specimens in the storage cylinder for removal and fixation. This protects staff from the sharp jaws and patient contaminants.
- Straighten the endoscope bending section and remove the 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 tip should only contact the desired hot biopsy site. Apply cautery using power settings appropriate for the electrosurgical unit. When the lesion is cauterized free the biopsy from the tented mucosa by retracting the jaws into the storage cylinder as described above. This automatically moves the specimen in the storage cylinder. The multibiopsy is now ready for the next hot or cold biopsy. Record the biopsy in the log.

Preferred Method for Clean and Efficient Use of Curlew Multibiopsy

After completing the biopsy sequence the endoscope is removed with the multibiopsy in place for transport to the cleaning area. There remove the multibiopsy from the endoscope, separate the storage cylinder and place in fixative with the Curlew label for transport to pathology with the labeled log. This method minimizes endoscopy suite soiling, protects staff and speeds turnaround.

Collection and Fixation of Individual or Batched Multibiopsy Specimens

- Collection of individual specimens: Each biopsy specimen is held within the biopsy jaws until pushed into the storage cylinder by the subsequent biopsy. Individual specimens may be collected from the sharp biopsy jaws by removing the multibiopsy from the endoscope, opening the jaws and placing the specimen in fixative. Wash and reuse only on the same patient.
- Collection of Specimen Batches: Specimens batches may be collected by retrieving the multibiopsy and irrigating the specimen batch from the storage cylinder into fixative. Retract the thumb ring to open the jaws. Place a blunt 22G needle on a 3ml syringe in a proximal storage cylinder perforation that is not blocked by the biopsy mechanism and irrigate into fixative. Wash and reuse only on the same patient.

Specimen Fixation in the Perforated Storage Cylinder for in Situ Processing

- 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 1 cm from the storage cylinder with a 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 storage cylinder as this may prevent specimen removal.

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.

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