

Curlew Endoscopic Multibiopsy

US Patents 5,782,747; 5,980,468; 6,071,248; 7,445,603 foreign patents and pending

Multibiopsy 9F with Plastic Storage Cylinder (C)

Hot and Cold or Cold 7, 13 or 25 Specimen

With in Situ Frozen Section, Paraffin or Microwave Processing

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 orients, serially collects and stores 2.0 mm diameter specimens in a removable perforated metal storage cylinder holding a removable internal perforated plastic cylinder for in situ fixation and pathological 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
- In pathology the perforated plastic storage cylinder (C) and last specimen held between the jaws are removed from the metal storage cylinder, processed by standard paraffin or microwave methods and microtomed in situ. Without fixation the plastic cylinder may be used for frozen section rapid diagnosis.
- The plastic internal cylinder doubles the number of specimens obtained by each instrument on the same patient. The first pass fills the internal cylinder that is removed in endoscopy and submitting for frozen section, microwave or paraffin processing. Then using the washed metal storage cylinder a second biopsy pass is taken for in situ paraffin processing.

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 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 stop.
- Jaw retraction automatically captures and stores the biopsy specimens in the perforated removable plastic or metal storage cylinder. This action: (1) retains specimens in the storage cylinder during withdrawal from the endoscope, fixation 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.

Simplified Precision

www.curlewendoscopy.com

vox 516-625-0965; fax 212-208-0949

Multibiopsy Operation in the Endoscopy Suite:

Preparation

- Curlew Multibiopsy 9F (C) requires a minimum 3.2 mm channel.
- Curlew Multibiopsy 9F Hot and Cold(C) or Cold(C) supports frozen section, paraffin or microwave or processing.
- Prepare the Curlew Multibiopsy Log (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 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.

For Cold Biopsy

- Place the multibiopsy 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 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.
- Retract the jaws fully into the storage cylinder by advancing the thumb loop to the handle stop.
- 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 hold 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 or Hot and Cold 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 wall and the multibiopsy tip. The metal hot multibiopsy should only contact the desired hot biopsy site. Apply cautery using power settings appropriate for the electrosurgical unit. Then with the thumb loop at the stop, free the biopsy from the tented mucosa. This automatically forces the specimen into the storage cylinder. The multibiopsy is now ready for the next hot or cold biopsy. Record the site and specimen number in the log.
- At completion retract the jaws completely into the storage cylinder by pushing the thumb ring to the stop to close the specimens in the storage cylinder during removal, fixation and handling in the pathology laboratory. Straighten the endoscope bending section and remove the Curlew Multibiopsy.

Two Biopsy Passes for Frozen Section and Paraffin Processed Specimens

- After the first pass remove the multibiopsy and retract the thumb loop to expose plastic storage cylinder within the biopsy mechanism. Remove the last specimen and the plastic storage cylinder. Wrap in paper as described below. Submit without fixation for frozen section or fix for microwave processing. Wash and repass to collect the second biopsy sequence in the metal storage cylinder for paraffin processing.

Two Biopsy Passes to Double the Number of Specimens (14, 26 or 50)

- After the first pass remove the multibiopsy and retract the thumb loop to expose plastic storage cylinder within the biopsy mechanism. Remove the last specimen and the plastic storage cylinder. Wrap in paper as described below.
- Wash and repass and obtain the second biopsy sequence in the metal storage cylinder.

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Removing the Perforated Metal Storage Cylinder for Fixation

- After separating the biopsy instrument from the endoscope maintain the jaws closed inside the metal storage cylinder by advancing the thumb ring to the stop. This prevents specimen loss and protects staff from sharps, potentially infectious tissue and solvents. Cut the black shaft and cable 1 cm from the metal storage cylinder with a wire cutter, place the metal storage cylinder in a labeled fixative vial and send to pathology with the labeled log. Do not cut or damage the metal cylinder as this may prevent specimen removal.

Removing and Paper Wrapping the Plastic Storage Cylinder

- Grasp the exposed last specimen and plastic cylinder with a fine tweezers and remove. Wrap the last specimen and plastic cylinder in lens paper with a graphite mark on the right indicating the last specimen to be placed away from the slide label. Place in Curlew labeled vial and transport to pathology unfixed or fixed.

A Preferred Method for Clean and Efficient Use of Curlew Multibiopsy

- Remove the endoscope from the patient with the multibiopsy in place for transport to the contaminated laboratory. There separate the multibiopsy and place the metal storage cylinder in a vial marked with the Curlew (C) label for transport to pathology. This minimizes endoscopy suite soiling and speeds turnaround.

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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