

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 Specimens

With in Situ Frozen Section, Microwave or Paraffin Processing

Pathology Laboratory Instructions for in Situ Processing

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 specimens in a removable perforated metal storage cylinder holding a removable 2mm diameter internal perforated plastic cylinder (C) for in situ fixation and processing with minimum handling and staff exposure to human material and solvents. The Curlew label on the fixative vial and labeled log completed by the endoscopist indicates the biopsy numbers, site, specimen number, acquisition sequence and indication for each specimen.
- For frozen section without fixation the plastic cylinder is removed from the metal storage cylinder and biopsy mechanism in the endoscopy suite for transport to pathology. A second pass of biopsies with the metal storage cylinder is submitted for permanent paraffin sections.
- For microwave processing either the fixed plastic cylinder or the fixed metal storage cylinder surrounding the biopsy mechanism and specimens in the perforated plastic storage cylinder (C) are sent to pathology. In pathology last specimen held between the jaws and plastic storage cylinder are removed from the metal storage cylinder wrapped, processed by microwave and microtomed in situ. The accompanying labeled fixative vial and Curlew Log that identifies each specimen. The specimens appear on the microscope slide as serial sections of oriented specimens with the first specimen on the left adjacent to the label in the order of acquisition as documented in the Curlew Endoscopy Log.
- The plastic internal cylinder doubles the number of specimens obtained from a single patient. The first pass fills the internal plastic cylinder that is removed in endoscopy and submitted for frozen section, microwave or paraffin processing. Then using the washed metal storage cylinder a second biopsy pass is taken for permanent in situ paraffin processing.
- In situ processing minimizes handling, reduces specimen loss and damage and yields serial sections of oriented specimens identified for acquisition site and order.
- Gross specimen examination is delayed until the slides are read.

Endoscopy Preparation of Multibiopsy Storage Cylinder for In Situ Processing

- After biopsy completion the sharp jaws are retracted into the storage cylinder to prevent specimen loss and protect staff. The multibiopsy shaft is removed and the storage cylinder placed in fixative for transport to pathology. Perforations in the storage cylinder allow specimen fixation and in situ processing.

Simplified Precision

www.curlewendoscopy.com

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

Curlew Endoscopy Instrument Corporation
Multibiopsy 9F with Plastic Storage Cylinder

Pathology Laboratory Plastic Storage Cylinder (C) Processing

- The perforated plastic storage cylinder (C) contains 7, 13 or 25 oriented, serially collected, stored biopsy specimens for processing with minimum handling. The last specimen is held within the biopsy jaws.

For frozen section

- The unfixed perforated plastic storage cylinder is immediately ready to freeze and cut on the cryostat at a 30 degree angle.
- For a plastic cylinder inside a closed metal storage cylinder, see the accompanying illustrated instructions for opening the storage cylinder to expose the biopsy mechanism surrounding the perforated plastic storage cylinder containing the serially collected, oriented specimens. Grasp the exposed last specimen and plastic cylinder with a fine tweezers and remove. Freeze and cut on the cryostat at a 30 degree angle. See below for obtaining permanent paraffin sections from second pass metal storage cylinder.

For paraffin processing

- Fix and process the closed perforated metal cylinder through paraffin. To open the metal cylinder remove the processing cylinder from the embedding station paraffin bath and prepare to open the metal cylinder while the paraffin is soft. See the accompanying illustrated instructions for opening the storage cylinder to expose the biopsy mechanism surrounding the paraffin encased oriented specimens. Grasp the exposed opened sharp jaws by their edges to keep the jaws separated. Remove the biopsy mechanism surrounding the fragile paraffin embedded specimen column from the metal storage cylinder. While the paraffin is still soft spread the jaws, remove the specimen column and wrap with a graphite mark on the right indicating the last specimen. The wrap keeps the specimen column in line and prevents column disruption when placed in hot paraffin for mounting. Mount the wrap and cut at 30 degrees on the microtome. Place multiple serial sections on each slide.
- The graphite mark adjacent to the last specimen is placed to the right of the slide away from the label. The specimen on the left adjacent to the label is "Biopsy 1" as documented on the Curlew Multibiopsy Log. The first biopsy specimen can also be identified by its separation from the biopsies compressed inside the storage cylinder. The serially sectioned oriented specimens on the slide are in the order of acquisition from left to right.

For microwave processing

- A fixed perforated plastic cylinder and last specimen are ready to wrap and microwave process.
- For a plastic cylinder inside a closed metal storage cylinder, see the accompanying illustrated instructions for opening the storage cylinder to expose the biopsy mechanism surrounding the perforated plastic storage cylinder containing the serially collected, oriented specimens. Grasp the exposed last specimen and plastic cylinder with a fine tweezers and remove. Wrap the last specimen and plastic cylinder with a graphite mark on the right indicating the last specimen to be placed away from the slide label. Microwave process through paraffin. Mount the wrap and cut at 30 degrees on the microtome..

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.

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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