


Single Use Curlew™ Multiple Biopsy Forceps

Pathology Laboratory Instructions

For In Situ Fixation, Frozen Section, Paraffin or Microwave Processing


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





INSTRUCTIONS FOR USE

Read this document in its entirety prior to use

Rx Only

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

 **Warning:** This Device is Sharp! Use same care as for any other surgical device to avoid punctures or cuts to hands, gloves, etc.

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

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Indications:

- Biopsy forceps are intended for use in collecting tissue samples for histological examination.

Contraindications:

- None known within the scope of the indicated use.



Warning:

- For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury, illness or death.

Overview:

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- The Curlew Multiple Biopsy forceps collects and stores up to 13 biopsies 2.0mm in diameter in a separable perforated plastic storage cylinder (cassette) within a perforated metal storage cylinder for in situ fixation and transport to pathology with minimum handling.

 - The labeled fixative vial and Curlew Multiple Biopsy Endoscopy Log (last page of IFU) indicate the number of biopsies, biopsy site, acquisition sequence and indication for each specimen.

 - The perforated plastic storage cylinder (cassette) is used unfixed for frozen section or fixed for paraffin or microwave processing. The thin plastic storage cylinder (cassette) is designed to be cut on the microtome with specimens in situ. In situ processing yields sections of oriented specimens with minimal handling, specimen loss, or damage (Identified by acquisition site, biopsy sequence and indication in the Curlew Multiple Biopsy Endoscopy Log).

 - With in situ processing, gross specimen examination is delayed until the slides are read.

 - For frozen section without fixation, the plastic storage cylinder (cassette) is removed from the biopsy mechanism in the endoscopy suite for transport to pathology. A second set of biopsies with the metal storage cylinder is submitted for permanent paraffin sections (See Microwave Processing and Paraffin Processing of Specimens from Metal Storage Cylinder).

 - For microwave or paraffin processing, the fixed perforated plastic storage cylinder (cassette) is removed from the biopsy mechanism and sent to pathology. Additional biopsy specimens taken with the metal storage cylinder may be obtained from the same single patient (See Microwave Processing and Paraffin Processing of Specimens from Metal Storage Cylinder).

Pathology Laboratory Plastic Storage Cylinder (Cassette) Processing:

- The perforated plastic storage cylinder (cassette) contains 13 oriented, collected, stored biopsy specimens for processing with minimal handling. The last specimen is held within the biopsy jaws.

Frozen section:

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- The unfixed perforated plastic storage cylinder (cassette) is immediately ready to freeze and cut at a 30 degree angle on the cryostat.

Microwave processing of the fixed perforated plastic storage cylinder (cassette):

- The fixed perforated plastic storage cylinder (cassette) and last specimen are ready to wrap and microwave process.
- On the wrap, place the last free specimen on the right adjacent to a graphite mark. Place the split end of the plastic storage cylinder (cassette) on the right, adjacent to the last specimen. Microwave process through paraffin. Mount the wrap with the graphite mark on the right. Cut at 30 degrees on the microtome. Mount multiple sections on each slide with the graphite mark on the right, away from the label.
- The specimen on the left adjacent to the label is "Biopsy 1" as documented on the Curlew Multiple Biopsy Endoscopy Log (last page of IFU). The last biopsy can also be identified by its separation from the biopsies, compressed inside the storage cylinder. The sectioned oriented specimens on the slide are in the order of acquisition from left to right.

Microwave processing of specimens removed from the metal storage cylinder:

- For fixed specimens in a metal storage cylinder, place the last free specimen to the right on the wrap. Hold the black shaft stub to the left. Grasp the sharp jaws and withdraw the biopsy mechanism surrounding the specimens. Spread the sharp jaws, remove and wrap the specimens. This option obviates the in situ processing features of orientation and collection of the plastic storage cylinder (cassette).
- Mount multiple sections on each slide with the graphite mark on the right, away from the label.


Paraffin processing of specimens in the fixed perforated plastic storage cylinder (cassette):











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- The fixed perforated plastic storage cylinder (cassette) and last specimen are ready to wrap and paraffin process.
 - On the wrap, place the last free specimen on the right, adjacent to a graphite mark. Place the split end of the plastic storage cylinder (cassette) on the right, adjacent to the last specimen. Process through paraffin. Mount the wrap with the graphite mark on the right. Cut at 30 degrees on the microtome. Mount multiple sections on each slide with the graphite mark on the right, away from the label.
 - The specimen on the left adjacent to the label is "Biopsy 1" as documented on the Curlew Multiple Biopsy Endoscopy Log (last page of IFU). The last biopsy can also be identified by its separation from the biopsies compressed inside the storage cylinder. The sectioned oriented specimens on the slide are in the order of acquisition from left to right.

Paraffin processing of specimens in the fixed metal storage cylinder:

- Place the last free specimen on the right, adjacent to a graphite mark. Hold the black shaft stub to the left. Grasp the sharp jaws and withdraw the biopsy mechanism surrounding the specimens. Spread the sharp jaws, remove and wrap the specimens. This option obviates the in situ processing features of orientation and collection of the plastic storage cylinder (cassette).

Disposal:

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

	Consult Instruction for Use
	Warning - Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	Caution - Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
	Single use - Do not reuse
	Ethylene Oxide Sterilization
	Catalog Number / Product Code
	Lot Number
	Use by Date
Rx Only	Federal (USA) Law restricts this device to sale by or on the order of a physician
	Authorized Representative
	Manufacturer

CURLEW MULTIPLE BIOPSY ENDOSCOPY LOG

Sample #	Organ	Biopsy Site	Comments
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			

Data Entered By: _____

Date Entered: _____

Patient DOB: _____

Patient Name: _____

PLACE PATIENT LABEL HERE

CURLEW MULTIPLE BIOPSY ENDOSCOPY LOG

Sample #	Organ	Biopsy Site	Comments
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			

Data Entered By: _____

Date Entered: _____

Patient DOB: _____

Patient Name: _____

PLACE PATIENT LABEL HERE