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# Single Use Curlew™ Multiple Biopsy Forceps

## 13 SPECIMEN WITH PLASTIC STORAGE CYLINDER (CASSETTE)

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

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## INSTRUCTIONS FOR USE

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*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.

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### 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.

### Inspection:

-  **Warning:** Inspect the package containing the forceps. If any damage is noticed, do not use the instrument as sterility may be compromised.
- Peel open the pouch and remove the forceps. Visually inspect the forceps for kinks, loose or broken parts. With forceps coiled in 8 inch loops: (2) for 230cm; (1) for 160cm; (1) for 110cm, verify forceps operate freely with no hesitation, and smoothly with no grinding, friction or clicking.
- Note the removable plastic storage cylinder (cassette) visible between the jaws and short 3mm movement necessary to advance and retract the sharp jaws. Observe that the jaws and plastic storage cylinder (cassette) retract fully into the storage cylinder when the thumb ring is advanced to the handle stop.
-  **Warning:** Do not use if any abnormalities are found or if the instrument is not operating properly.

### Device Overview

- The Curlew Multiple Biopsy forceps collects and stores up to 13 biopsies 2.0mm in diameter in a separable perforated plastic storage cylinder (cassette) for in situ fixation and transport to pathology with minimum handling and staff exposure to human material, sharps and solvents.
- **In situ fixation** is fixation of the entire 13 specimen biopsy series within the plastic storage cylinder (cassette) or the metal storage cylinder. This minimizes the work, exposure to sharps and human material previously required to separate the biopsies from the biopsy device in endoscopy. The removable plastic storage cylinder (cassette) maintains the collected, oriented cylinder stored specimens in acquisition order as documented in the

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Curlew Multiple Biopsy Endoscopy Log (Attached to last page of the Pathology Laboratory Instructions) through histopathological processing with minimum handling in pathology. Multiple sections are mounted on slides in acquisition order for reading by the pathologist. The plastic storage cylinder (cassette) is used for rapid diagnosis by frozen section or microwave processing.

- Curlew Multiple Biopsy forceps requires a minimum 3.2mm endoscope channel.
  
- For biopsy the jaws are pushed out of the storage cylinder and inserted into the tissue to surround the specimen. During jaw closure and retraction, biopsies are cut, captured, oriented and collected in the storage cylinder in acquisition order. This action: (1) retains specimens in the storage cylinder during and after endoscope withdrawal, during in situ fixation and transport to pathology; (2) protects staff during multiple biopsy use; (3) prevents endoscope instrument channel damage during passage and withdrawal.
  
- The label on the pouch and fixative vial indicate the maximum number of specimens collected in a single endoscopic pass and held in the storage cylinder for in situ fixation.
  
- The Curlew Multiple Biopsy Endoscopy Log (Attached to last page of the Pathology Laboratory Instructions) completed by the endoscopist identifies the number of specimens, biopsy sites, acquisition order and indications to the pathologist.
  
- In situ fixation and processing within the plastic storage cylinder (cassette) maintains the oriented, collected, stored specimens in the order of acquisition to the slide. The plastic storage cylinder (cassette) is designed to be cut on the microtome for frozen section, or after paraffin or microwave processing.
  
- After removing the plastic storage cylinder (cassette) with 13 specimens, an additional 13 specimen pass can be taken with the metal cylinder for in situ fixation (only on the same patient). Then multiple passes of up to 13 specimen for removal by irrigation without situ fixation can be taken (only on the same patient).
  
- For rapid diagnosis by frozen section prepare a specimen vial without fixative.
  
- After collecting plastic storage cylinder (cassette) specimens for frozen section perform a second biopsy pass with the metal storage cylinder for permanent sections.

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**Operation:**

- **For hot multiple biopsy forceps;** connect an Olympus compatible active cord to the instrument and ensure the connection is tight. Inspect the active cord for kinks, bends, breaks and exposed wires. If any abnormality is found, do not use the cord. The cord should snap onto the handle. If the cord is loose, call your sales representative who can provide you with the proper cord. Connect the other end of the cord to the electrosurgical generator and follow the manufacturer's instructions regarding operation and proper grounding.
-  **NOTE:** IT IS IMPORTANT TO USE AN OLYMPUS COMPATIBLE PLUG. OTHER PLUG CONFIGURATIONS CAN LEAD TO FAULTY OPERATION.
-  **Warning:** Connection to equipment not complying with EN 60601-2-2 could compromise patient safety.
  
- Prepare the Curlew Multiple Biopsy Endoscopy Log (Attached to last page of the Pathology Laboratory Instructions) to record the site, sequence and indication of each biopsy.
  
- 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.
  
- Do not open and close the jaws without straightening the shaft as that may alter the precise biopsy action.
  
- Observe that the jaws retract fully into the biopsy storage cylinder when the thumb loop is advanced to the handle stop.
  
- Full jaw retraction ensures that the endoscope instrument channel is not damaged during passage or withdrawal and that the biopsy specimens are retained in the storage cylinder during withdrawal from the endoscope. Close the forceps jaws before inserting the instrument into a 3.2mm endoscope channel. Use short motions when inserting the forceps to avoid kinking.
  
- If the scope is equipped with an elevator, lower the elevator fully before loading.

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- If resistance is met when the bending tip of the forceps is angulated, release the bending angle slightly until the instrument passes smoothly. Do not force the forceps into an angulated scope as this could damage the endoscope.
  - To take a biopsy, place the instrument tip close to the desired biopsy site and gently retract the thumb loop to extend the jaws while visualizing the procedure through the scope.
  - Advance the open jaws into the tissue to surround the biopsy site.
  - Close the jaws by gently advancing the thumb loop to the handle stop. The closing jaws cut, capture, orient and store the specimen in the storage cylinder, in the order of acquisition.
  - Inspect the biopsy site for bleeding mucosal defect indicating biopsy capture. Capture failure is caused by not inserting the open jaws into the tissue as with a biopsy pin. Note the biopsy site, sequence and indication on the Curlew Multiple Biopsy Endoscopy Log (Attached to last page of the Pathology Laboratory Instructions).
  - Repeat until up to 13 biopsies, or the desired number of biopsies, are obtained.
  -  **Caution:** Do not use excessive force to close the jaws as this could damage the instrument.
  - When the biopsy sequence is complete, fully retract the jaws into the biopsy storage cylinder and slowly withdraw the instrument from the scope while keeping the jaws closed. If the scope has a forceps elevator, it must be lowered before withdrawing the forceps.
  - If the jaws will not close completely, do not force the forceps out of the endoscope. Remove the endoscope with the forceps still in place and then manually close the jaws before removing the instrument from the scope.

**Removing the Plastic Storage Cylinder (Cassette) with 13 Biopsies:**

- After collecting 13 biopsies remove the Multiple Biopsy forceps from the endoscope.

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- Over the empty vial for frozen section or fixative vial for paraffin or microwave processing, retract the thumb loop to expose plastic storage cylinder (cassette) between the jaws. Remove the last specimen held between the jaws and then remove the plastic storage cylinder (cassette) with a fine tweezers. Place in the labeled vial and transport to pathology with the Curlew Multiple Biopsy Endoscopy Log (Attached to last page of the Pathology Laboratory Instructions).

**Metal Storage Cylinder Retrieval and Fixation of Batched or Individual Multiple Biopsy Specimens**

- After removing the biopsy instrument from the endoscope, keep the jaws closed inside the metal storage cylinder by pressing the thumb loop against the handle stop. This prevents loss of the specimens and protects staff from contact with sharps, jaws and potentially infectious tissue or fluid.
- With the storage cylinder over the fixative vial, retract the thumb loop to open the storage cylinder. Cut the black cable ½ inch from the metal storage cylinder with a heavy wire cutter. (Do not cut or damage the metal cylinder as this may prevent specimen removal in pathology.) Place the metal storage cylinder in labeled fixative vial for transport to pathology. Affix a matching label to the Curlew Multiple Biopsy Endoscopy Log (Attached to last page of the Pathology Laboratory Instructions) for transport to pathology.

**Batch Collection of Specimens without in situ fixation:**  
**(Irrigation of specimen batches from the storage cylinder into fixative)**

- Prepare a blunt 20G needle on a 3ml syringe filled with fixative. Remove Multiple Biopsy forceps device from the endoscope and hold the storage tip over the fixative vial.
- Retract the thumb loop to open the storage cylinder. Identify an open proximal storage cylinder hole (not blocked by forceps mechanism).
- Insert irrigation needle in an open proximal storage cylinder hole. Irrigate specimens into fixative. Examine the storage cylinder to ensure all specimens have been removed. Repeat if specimens remain.

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**Single Specimen Collection without in situ fixation:**

- 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 Multiple Biopsy forceps from the endoscope, opening the jaws and placing the specimen in fixative.

**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.

**Storage:**

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

**Warranty:**

- Endo-Therapeutics Inc. warrants that the instrument will be free from defects in materials and workmanship for use in a single procedure.

This warranty does not apply to 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. Endo-Therapeutics' obligations under this warranty are limited to the replacement of the instrument.

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### Symbols used on labeling

	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
<b>Rx Only</b>	Federal (USA) Law restricts this device to sale by or on the order of a physician
	Authorized Representative
	Manufacturer