

MultiBiopsy-13:

Disposable Endoscopic Multiple Biopsy Instrument

New Multiple Biopsy Technology Increases Endoscopy Efficiency and Safety

- *Full patient care cycle efficiencies improve care and reduce costs*
- *Meets requirements of accountable care mandate*
- *Scalable to all areas of tissue acquisition and endoscopic procedures*

Innovation for Endoscopic Specimen Acquisition

Shortened endoscopic procedure ~ Improved Biopsy ~ Faster Diagnosis and Therapy

- **FDA: Registered cold and hot multiple biopsy; CE: In Process**
- **New tissue cutting biopsy technology controls biopsy depth (1.87 ± 0.05 mm)**
- **Reliable Biopsy: Visible confirmation of specimen acquisition from mucosal defect**
- **Multiple Biopsy: Single pass 13 specimen model - 9F (3.2mm channel) – cold or hot and cold**
- **Rapid Diagnosis by removable plastic liner for Frozen Section or Microwave Processing**

The TIP Secret: - Integrated Tissue Acquisition and Processing:

- **Tip collects and stores oriented biopsies in the order of acquisition**
- **Cut the tip from the device for processing ~ *No specimen handling required***
- **Tip stores biopsies during transport and pathological processing**
- **Curlew Log documents acquisition order, biopsy site, indication and diagnosis for pathologist**

Advantages for Pathology

- **No specimen handling required prior to processing in Curlew instrument tip**
- **Specimen orientation and order maintained from acquisition to microscope slide**
- **Multiple oriented specimen sections presented on single slide for improved diagnosis**
- **Increases specimen number available per indication and biopsy site**
- **Reduces slide fabrication work and cost**

Benefits to the Full Care Cycle

- **Hospitals- reduced costs, less liability risk, faster diagnosis, faster therapy, shorter stay**
- **ASUs- less staff work, less workplace risk, more patients serviced; more income**
- **GI Physicians- less procedure risk, less work, more patients serviced, more income**
- **Anesthesiologists- more cases, fewer complications; less PACU supervision**
- **Pathologists – better diagnostic information, faster processing, less work**
- **Patients- less risk, less anesthesia, faster recovery, faster diagnosis and therapy**

For more information see www.curlewendoscopy.com

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Multibiopsy-13: Patient Care Benefits

Improved Procedural Safety and Efficiency

- Multiple biopsies in a single endoscopic pass shorten procedures
- Biopsy depth control minimizes patient risk from bleeding or perforation
- Shorter procedures: less anesthesia, faster patient recovery, less patient risk
- Faster diagnosis (1-2 hours) available using Curlew storage cylinder for immediate frozen section or microwave processing

Faster Biopsy Acquisition Reduces Procedure Times

- Shorter procedures reduce anesthesia time, cost and patient risk
- Less anesthesia shortens recovery and time in PACU
- Less PACU supervision increases staff efficiency
- Shorter procedures and less PACU increase patients serviced

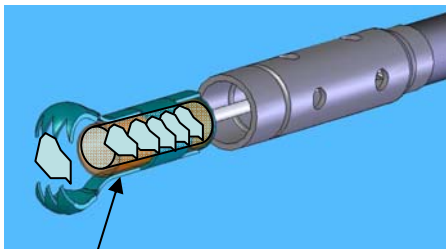
Tissue Acquisition with Minimal Handling via Removable Storage Tip

- Reduced assistant work compared to removing individual biopsies into fixative
- Reduced workplace risk:
 - ◊ Less suite soiling reduces cross infection risk from *C. difficile*
 - ◊ Less exposure to sharps, infectious material and fixatives-formalin
- Improved workplace cleanliness reduces clean up and speeds turn around

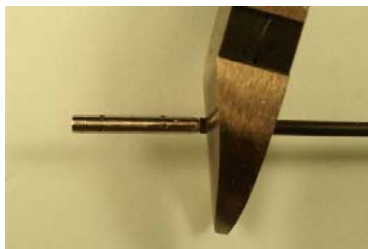
Pathology Efficiencies of “In-Tip” Specimens Processing

More rapid processing and interpretation speeds therapy for improved care

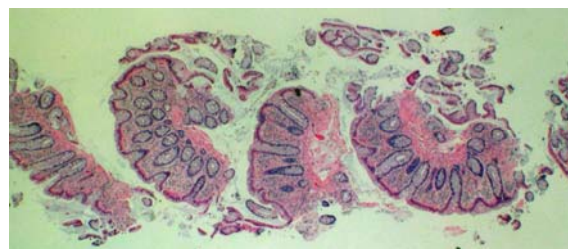
- Oriented specimens immediately processed in the Curlew “tip.”
- Minimal handling required; no grossing, filtering or orientation.
- Multiple oriented serial sections mounted on each slide
- Faster processing with reduced work
- Specimen orientation with serial sections facilitates interpretation and diagnosis



1) Tip captures & stores biopsies in order of acquisition.



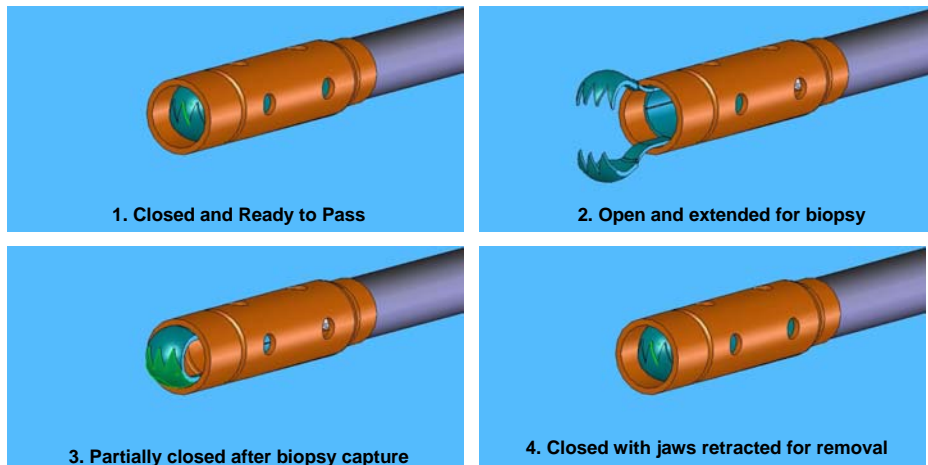
2) Tip cut from instrument after procedure for transport to & processing in the lab.



3) Single diagnostic slide with multiple oriented biopsies.

CURLEW MULTIBIOPSY-13

Instrument Deployment




1. Closed and Ready to Pass

2. Open and extended for biopsy

3. Partially closed after biopsy capture

4. Closed with jaws retracted for removal

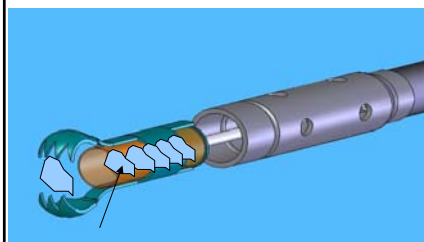
5. Repeat



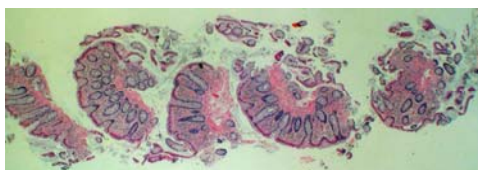
Curlew
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SERIAL COLLECTION BENEFITS

- SPECIMENS COLLECTED IN TIP IN ORDER OF ACQUISITION
- ORIENTATION MAINTAINED
- ALLOWS MAPPING OF BIOPSY SITE DYSPLASIA OR NEOPLASIA
- FACILITATES COMPARATIVE EVALUATION OF BIOPSY SERIES
- REDUCES SLIDE COUNT IN PATHOLOGY

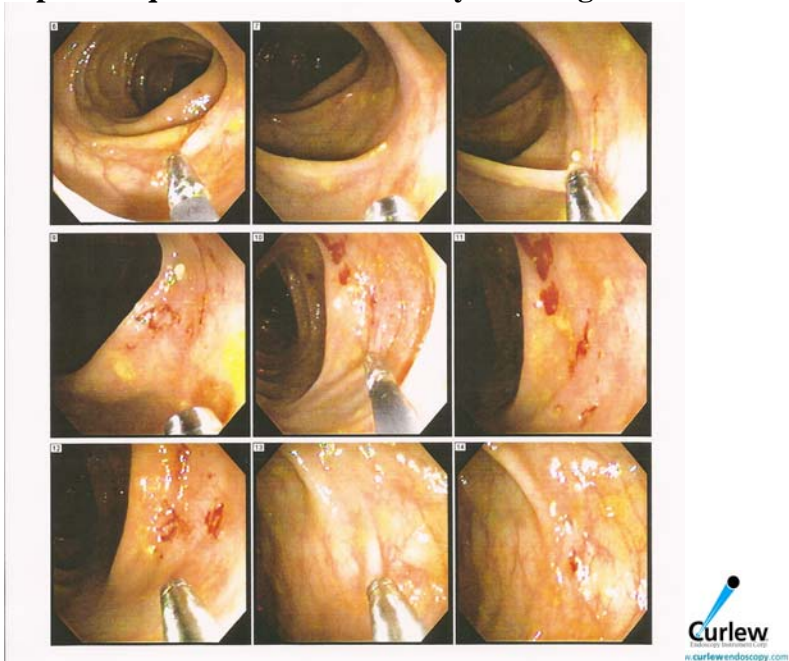


Biopsies captured and stored in order

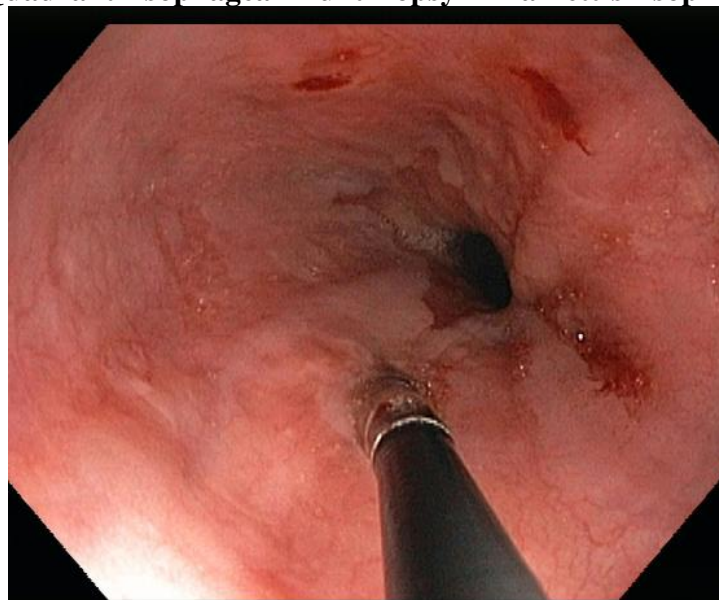


Orientation and order maintained through slide production

9 Colon biopsies acquired and identified by bleeding mucosal site

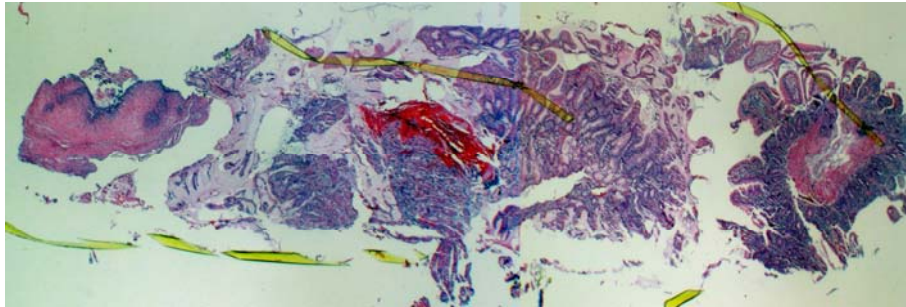


4 Quadrant Esophageal Multibiopsy in Barrett's Esophagus



MultiBiopsy in Upper Gastrointestinal Endoscopy:

- Right Specimen – duodenal
- Center Specimen – gastric
- Left Specimen – esophageal
- Plastic storage cassette (yellow)



A Curlew Log identifying specimen site and indication is completed during tissue acquisition, and transmitted with specimens.

Curlew Endoscopy MultiBiopsy Log
9F 25 Specimens
www.curlewendoscopy.com

Patient Name _____
Patient # _____
Date _____

Colonoscopy Surveillance 25 Specimens

Sample	Organ	Biopsy	Site	Indications	Comments
1	Ileum				
2	Cecum	Dorsal			
3	Cecum	Ventral			
4	Cecum	Medial			
5	Cecum	Lateral			
6	Right Colon	Dorsal			
7	Right Colon	Ventral			
8	Right Colon	Medial			
9	Right Colon	Lateral			
10	Trans	Dorsal			
11	Trans	Ventral			
12	Trans	Medial			
13	Trans	Lateral			
14	Left Colon	Dorsal			
15	Left Colon	Ventral			
16	Left Colon	Medial			
17	Left Colon	Lateral			
18	Sigmoid	Dorsal			
19	Sigmoid	Ventral			
20	Sigmoid	Medial			
21	Sigmoid	Lateral			
22	Rectum	Dorsal			
23	Rectum	Ventral			
24	Rectum	Medial			
25	Rectum	Lateral			



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Comparison of Current Biopsy Specimen Processing to Curlew Multiple Biopsy Processing

Endoscopy Specimen Acquisition and Handling:

	<u>Single Biopsy Specimens</u>	<u>Multibiopsy Specimens</u>	<u>Difference</u>
Biopsy passes	1 pass / specimen (add 1-3 min/pass)	single pass: 1- 13 specimens	saves time/work/cost workplace soiling & risk
Specimen retrieval into fixative jar	1 by hand per each biopsy pass segregated by biopsy site	MultiBiopsy tip removal plastic removable cassette	time - work less workplace risk less biopsy damage
Specimen Damage	specimens damaged in handling	Minimal Handling/No Damage	diagnostic information retained
Identification	jar labels-pathology form	Curlew Log	saves time/ work
Transport Pathology	Single or multiple jars w/ labels [1 jar/ 1 biopsy site]	single jar w/ tip + log [1 jar / up to 13 biopsies from multiple sites]	saves time/work/cost

Pathology Handling, Processing to Slide and Diagnostic Interpretation:

	<u>Single Biopsy Specimens</u>	<u>MultiBiopsy Specimens</u>	<u>Difference</u>
Accession	Single or multiple jars	single MultiBiopsy tip with Log or internal cylinder	saves time/work/cost
Processing preparation	By hand for each specimen(jar) Filtration of each jar specimens into paper wrap and place in labeled cassette	Minimal: Simple transfer of MultiBiopsy tip or cylinder to processing cassette	saves time/work/cost less biopsy damage workplace risk
Paraffin Processing	6-8 hours in multiple processing cassettes	6-8 hours single cassette	none
Frozen Section	Not available	60 minutes	rapid diagnosis
Microwave Processing	2 hours multiple cassettes	2 hours 1 cassette w/ 1 MultiBiopsy cylinder	none

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Comparison of Current Biopsy Specimen Processing to Curlew Multiple Biopsy Processing

Pathology Handling, Processing to Slide and Diagnostic Interpretation (cont.):

	<u>Single Biopsy Specimens</u>	<u>Multibiopsy Specimens</u>	<u>Difference</u>
Specimen orientation	as requested by hand	automatic for all MultiBiopsy specimens	saves time/work/cost
Mounting for microtome	single or multiple batches (each specimen handled)	single mount of 13 specimen column serially collected in acquisition order	saves time/work/cost
Sections from microtome	single or multiple slides	single slide of multiple serial sections oriented in acquisition order	saves time/work/cost
Slide(s) stain and mount	single or multiple slides	single slide	saves time/work/cost
Slide Cost	\$4.66 each slide produced	fewer slides	saves \$4.66 for each slide not fabricated
Slides read	single or multiple slide(s)	single slide, specimens oriented, Serial sections	saves time/work improved diagnostic info.
Disease site correlation	by batch	by individual specimen	Improved diagnostic info.
Diagnostic accuracy	current	improves ability to map sites	improved diagnostic accuracy
Diagnostic speed	paraffin (12 -24 hrs) or microwave processing (2-4 hrs)	microwave(2-4 hrs) or frozen section (1 hr)	saves time/cost faster diagnosis & therapy