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The Perils of cross contamination in flexible endoscopes: Reusable versus single use valves, ports and tubing

Guest Presenter:
V. Robin O. Novak, RN CIC

Infection Prevention Conference

2½-days designed for ASCs and their infection prevention needs!

Wednesday, Thursday & Friday
October 5-7, 2016

Red Rock Casino Resort & Spa
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Disclosure:

This program is a collaboration between Excellentia Advisory Group and the generosity of an EndoChoice sponsorship.

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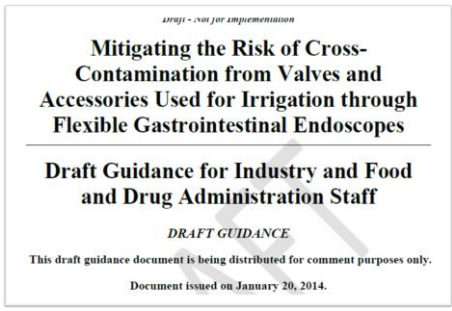
Additional Handouts
FDA Draft Guidance



Draft - Not for Implementation

Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation through Flexible Gastrointestinal Endoscopes

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on January 20, 2014.

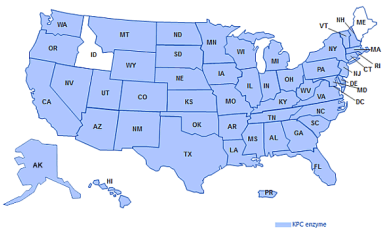
Objectives:

The learner will be able to:

- Identify key changes to the AAMI ST-91 and the SGNA Standards for infection prevention in reprocessing of flexible gastrointestinal endoscopes and how it will impact GI endoscopy settings.
- Identify key criteria in decision making for 24-hour versus single-use devices.
- Apply key decision making matrices to assist in the implementation of disposable devices through the infection control risk assessment

Flexible endoscopes present many reprocessing challenges

States with KPC-producing Carbapenem-resistant Enterobacteriaceae (CRE) reported to the Centers for Disease Control and Prevention (CDC) as of February 2015



This map was last updated on February 2015

Spaulding classification system

Device Classification	Examples	Spaulding process classification	EPA product classification
Critical (Enters sterile tissue or vascular system)	Implants, scalpels, needles, other surg. Instruments	Sterilization: sporicidal chemical; prolonged contact	Sterilant/ disinfectant
Semi critical (Touches mucous membranes)	Flexible endoscopes, laryngoscopes, ET tubes, vaginal specula	High Level Disinfection: sporicidal chemical; short contact	Sterilant/ disinfectant
Non critical (touches intact skin)	Stethoscopes, tabletops, blood pressure cuffs	Low level disinfection	EPA reg. hospital disinfectant

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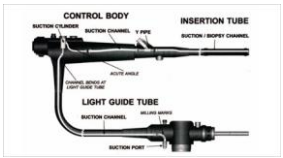
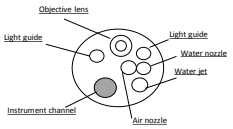




ANSI/AAMI ST91:2015

Society of Gastroenterology Nurses and Associates, Inc.

Poll Question

- Are you aware that the updated SGNA reprocessing standard includes a "safety stop"?
  - Yes
  - No

Reprocessing steps

- Pre-cleaning at point of use
- Transport
- Manual/ mechanical leak testing
- Manual cleaning
- Rinse

Reprocessing steps

- Inspecting/ testing for cleanliness

A.K.A.

"Safety stop" or "Time Out"

Reprocessing steps

- High level disinfection
- Rinse
- Alcohol flush
- Dry
- Storage

VALVES, PORTS, CONNECTION TUBING

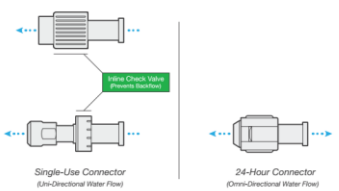
- Remove all valves and biopsy port covers, keeping with the scope throughout the process
- Endoscope valves need to be manually actuated to ensure coverage of all internal parts
- Cleaning brushes should either be single use and disposed of or reusable and receive high-level disinfection or sterilization after each use
  - Correct size based on channel size and manufacturer written instructions for use
- Soak, scrub, brush and rinse all reusable and removable parts (valves, buttons, port covers, tubing)

❖Suction valve
❖Small opening on metal shaft only accessed when button is depressed/ actuated

❖Air/ water valve
❖O-rings
❖Silicone skirt

❖ Biopsy port
❖Ridges and grooves

Auxiliary Water Jet Connectors



❖Water bottle, irrigation and connecting tubing

What you should know about 24 Hour Connectors

- A 24 hour connector doesn't have a check valve to prevent back flow.
- It is 100% reliant on technique (i.e., priming the irrigation channel) to prevent backflow.
- Ongoing studies are looking into concerns re: backflow - resulting in the connector and the irrigation tubing becoming contaminated.

How does this Differ from a single-use connector ?

- A check valve is present which prevents back flow to the irrigation tubing.
- Therefore, if back flow occurs up the irrigation channel of the endoscope, only the connector is contaminated.
- The connector is removed at the end of the procedure, and the irrigation tubing is safe to reuse for the next procedure.

Automatic Endoscope Reprocessor (AER)

- Verify compatibility of endoscope and components
- Automated cleaning cycle is not intended to replace point of use pre-cleaning or thorough manual cleaning of the endoscope prior to placing it into the AER
- Can the AER effectively process the endoscope and components (Valves, ports, elevator guide wire channel) or will this need to be performed manually?

Logistics of keeping/ tracking valves with a specific endoscope

Remove all valves and biopsy port covers, keeping with the scope throughout the process

- Time?
- How? Special container? Mesh bag?
- How will the container/ mesh bag be processed and identified?
- Has the container/ mesh bag been validated for processing? Or will it need to be single use disposable?
- Storage requirements? Adequacy? Temperature/ humidity
- How will container/ bag be labeled for identification in event separated from endoscope?

Documentation

- "Document the introduction and withdrawal from use of all endoscopes, endoscope accessories, AERs and AER accessories such as endoscope connection devices and sterilizers" (AAMI, pg 36)

Poll Question

- What manufacturer brand of endoscopes does your facility utilize?

A Olympus

B Pentax

C Fujinon

"Cost is important, but patient safety should be the overriding factor when choosing any type of medical device."

Determining if disposable devices are a fit for your facility

Determine:

- number of "reusable" device on hand
- frequency "reusable" device replaced due to normal wear and tear
- price of replacement "reusable" device
- approximate average number of uses for "reusable" device
- approximate time required for reprocessing "reusable" device
- Are disposable devices available?
- Have disposable devices been
  - FDA approved
  - Compatible with endoscope and endoscope components
- Storage capacity for disposable device
- Availability of disposable device
- Alternatives (backup) in event disposable device on backorder

Sample cost comparison of reusable

Device	Price/ reusable	# endoscope components on hand	Min # reusable on hand	# reusable ordered/ year (set time frame)	Total # reusable for 1 year	$ amount on hand	$ amount ordered/ year	Total $/ year	Ave # endo cases/ mo	Ave # endo cases/ year	Cost of reprocessing (time [30 min] + chemicals)/ case	Cost of reprocessing (time [30 min] + chemicals)/ year	approx. cost/ case
Biopsy port	$2.00			22	40	$36.00	$44.00	$80.00					
Suction Button	$75.00			7	25	$1,350.00	$525.00	$1,875.00					
Air/ water Button	$100.00	16	18	7	25	$1,800.00	$700.00	$2,500.00	250	3000	$10.00	$30,000.00	$11.69
Water Jet Tubing	$24.00			7	25	$432.00	$168.00	$600.00					
TOTAL	$201.00					$3,618.00	$1,437.00	$5,055.00					

All data is for illustration purposes only. Performance of individual cost comparison is required

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Sample cost comparison of disposable

Device	Price/ Disposable	$ amount on hand	Ave # endo cases/mo	Ave # endo cases/ yr	Estimated total $/ year	Total estimated $/ case
Biopsy port	$1.00	$250.00	250	3000	$3,000.00	$8.90
Suction Button	$2.20	$550.00			$6,600.00	
Air/ water button	$2.20	$550.00			$6,600.00	
Water jet tubing	$3.50	$875.00			$10,500.00	
TOTAL	$8.90	$2,225.00			$26,700.00	

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Sample cost comparison of disposable

Device	Price/ Disposable	$ amount on hand	Ave # endo cases/mo	Ave # endo cases/ yr	Estimated total $/ year	Total estimated $/ case
Biopsy port	$1.00	$250.00	250	3000	$3,000.00	$8.90
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Poll Question

- Have you performed a cost comparison of reusable versus disposable valves, ports and tubing?
  - Yes
  - No
  - Don't Know

Infection Control Risk assessment

- Endoscope compatibility
- Instructions for use
- Increased BBP/ OPIM exposure risk?
- Storage conditions
- Training and competency
- Disposable device performance

Product Trial evaluation

Determining priority evaluation criteria:

- Poll end users for criteria
- Pare criteria to manageable, fundamental list
- Develop a simple rating scale 1-5
- Distribute formal evaluation form to end user to evaluate the device
- Calculate results
- Disseminate results to stakeholders

Product Evaluation

Product:

Purpose of Product:

Product is compatible with [Olympus], [Pentax], [Fujinon] endoscope

Please rate the following characteristics on a scale of 1-5. 1 is worst and 5 is best

Criteria	1	2	3	4	5	Comments
Ease of use						
Fits snugly						
Produces similar end results as original device.						
"Feel" is similar to original device						
BBP/ OPIM considerations?						
Special use considerations?						
Product provided is sterile?						
Special storage conditions?						
Other:						

Comments:

I prefer to use:

Criteria	1	2	3	4	5	Comments
Trial product						
Original product						
Something else: List						

Evaluated by: Date:

- Perform Infection Control Risk Assessment
- Perform Cost analysis
- Research options available based on facility endoscope
- Review supporting documentation, guidelines
- Evaluate resources
  - Who, what, where, when, why, time, training, competencies, space etc

MAKE A DECISION BASED ON EVIDENCE

REFERENCES:

- Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation through Flexible Gastrointestinal Endoscopes; FDA draft guidance, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM430550.pdf, accessed 1/18/2016
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QUESTIONS?

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INFECTION PREVENTION CONFERENCE

2½-days designed for ASCs and their infection prevention needs!

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