John Leahy
37096 Blue Bill Drive
Selbyville, DE 19975

October 30, 2015

CERTIFIED - RETURN RECEIPT

Catherine A. McMullen, Chief, Disclosure Unit
U.S Office of Special Counsel
1730 M Street, NW., Suite 300
Washington, DC 20036

Re.: OSC File No. DI-15-0563

Dear Ms McMullen:

This is in reply to yours of the 14th ult., with which you conveyed a copy of a report from the Department of Veterans Affairs (VA) in response to allegations I made related to the above referenced matter. You offered me the opportunity to read the VA's report of self-investigation and to respond with written comment. This is my comment. The VA Office of the Medical Inspector's response is preposterous and disingenuous.

If a private company purchased sophisticated equipment and failed to read and follow clear manufacturer-supplied instructions-for-use, and thus employed that equipment in a manner which endangered customers for a span of thirteen years in support of more than 52,000 customer interactions -- that would be branded gross negligence, at best.

My assertion was and remains that from 1995 or earlier, until August, 2008, the VA Medical Center in Washington, DC employed approximately 25 flexible endoscopes to support 4,000 ENT Clinic appointments per year without ever reading and following crystal-clear manufacturer's instructions which came in the box with each of those endoscopes. My initial assertion focused on failure to leak test flexible endoscopes for breaches in their insertions tubes prior to each and every use, as required by manufacturer instructions As unlikely as I know it must sound, and realizing that it's really beside my central point, I also assert the truth that my supervisor ordered me confined to my office without use of e-mail indefinitely in response to my drive to correct endoscope reprocessing deficiencies, and after I broached the question of notifying veterans of their dangerous exposure, and that she went so far as to remark that physical harm might come to me if I did not comply with my confinement. Incredible but true!

The VA's Office of Medical Inspector's lengthy response to my central allegations may be summarized as follows:

- The VA acknowledged that prior to August, 2008, flexible endoscopes were never leak tested for holes in their insertion tubes. (page ii).
- Despite the failure to leak test, the VA's investigators maintain that there was no significant patient risk for two reasons:
    1.The next physician to use the endoscope would have noticed evidence of damage and refrained from using a leaking endoscope on another patient (page ii), and
    2."Even in the absence of such evidence [of damage], the high level disinfectant fluids used in sterile processing would follow the same path via the leak site as any potentially biohazardous materials and would inactivate them."(page ii-iii)
- For the above reasons, failure to leak test did not, according to the investigators, pose a serious risk to public health (page iii)
- Furthermore, the VA asserted that I, myself, told them "that even before 2008 the instruments had been cleaned and disinfected according to the prevailing standards of the time." (page 8)
- Based on the above, the VA concluded that since (1) failure to leak test was not a significant hazard, and (2) all other aspects of high level disinfection were performed correctly, there was therefore no proof of significant risk that veterans had been cross-infected with disease.

My answer to this logic is this: With regard to the importance of leak testing, I offer first my personal experience which says that (1) holes in endoscope insertion tubes may not be noticed, or even seen, with the naked eye, (2) damage to fiberoptics from small fluid invasions may be minimal and may take long periods of time to develop, during which time the endoscope may be used on a succession of many patients, (3) because of the rubbery nature of the insertion tubes, some leaks are positional, not constant, so that the Cidex OPA disinfectant may not have the same access as the infected biomaterial, and (4) even if the Cidex OPA follows the biomaterial inside the insertion tube, Cidex OPA is well known to be potentially ineffective in the presence of biomaterial -- which, by the way, is why effective cleaning and enzymatic detergent treatment are so crucial prior to Cidex OPA disinfection. That is why I assert that failure to leak test is such a monstrous risk of cross-infection. Much compelling evidence supports this assertion. One example of many is the well documented case of a single upper endoscopy fiberoptic endoscope (which is what we're talking about here) that cross-infected nine patients with tuberculosis over a two and a half week period. (See my Attachment AA). The only thing noted as wrong with this endoscope was that it had a hole in its insertion tube. The only thing wrong with its disinfection was that it was not leak tested. The patients had no other contact with each other than that the endoscope was used on each of them subsequent to its being used on a TB patient. The cross contamination was confirmed with a DNA match of the TB in each patient. Evidently,

- For two and a half weeks, no endoscope user noticed the hole in the insertion tube or any evidence of internal damage,
- For two and a half weeks, with repeated high level disinfection, the disinfectant chemical did not enter the hole in the insertion tube and kill the TB.

If no one had discovered the TB cross contamination, eventually the user would have noticed a poor image from damaged fiberoptics. The endoscope would have been sent out for repairs. The repair vendor would have followed its protocol by leak testing the endoscope, replace the damaged insertion tube sheath, and the endoscope would have been returned to service until

such future time that another leak occurred. That would be the pattern of use and repair in the absence of leak testing. Imagine: If one endoscope could infect 9 patients over a two and a half week period, what about 25 endoscopes never leak tested in 52,000 appointments spanning 13 years?

The VA's response goes on to assert that I told them that failure to leak test was the only disinfection deficit prior to 2008. That is simply not true. What I told them was that in 2007 and 2008, failure to leak test was the worst error, and that prior to 2007, pretty much **every aspect** of disinfection of endoscopes and their related pumps and tubing and accessories was deficient since at least 1995. Prior to my rewriting all standard operating procedures in 2008, pumps, tubing and accessories, and even cleaning and disinfection of internal channels were **entirely overlooked** in ENT Clinic disinfection procedures!!! After my meeting with the VA investigators, I was concerned that they were intent on hearing only what they wished to hear, so I sent them an e-mail to make certain that I had communicated. (See attachment BB, copy of e-mail). The full text of this e-mail dated March 19, 2015, reads as follows:

"I am writing to make sure I have clearly communicated the information you requested today. As I said, I personally believe that the lack of leak testing prior to 2008 was the most significant issue endoscope disinfection. Just to be clear, other problems included :

- (1) before 2007 lack of timers for timing of cidex opa soak times,
- (2) before 2007 lack of a written sop [standard operating procedure],
- (3) before 2007 lack of a wall clock for timing of cidex test trip quality checks,
- (4) before 2008 use of MAJ-210 biopsy port covers on the PEF Type V scope
- (5) before 2008 lack of suction equipment,
- (6) before 2008 lack of leak testing equipment,
- (7) before 2008 lack of power outlets to support suction or leak testing,
- (8) before 2008 lack of temperature testing for cidex opa, and
- (9) lack of bioburden testing for the PEF Type V scope,
- (10) before 2008 lack of a MAJ-1219 cleaning adapter for the PEF Type V scope.

Regarding the infection risk inherent specifically in leaking endoscopes, here is one source of many:
http://www.psa.edu.my/cmet/publications/Digest/ENDOSCOPE%20LEAKAGE%20TESTER.pdf
[which says in part:]
"Infection Control Considerations
From an infection control perspective, proper leak testing is one of the most crucial and vital steps. Cross-infection is a risk if a leak is left unchecked. Retained organic soil can inactivate germicides. It can also prevent contact of the germicide with potentially contaminated surfaces. Both circumstances create an infection risk. If a scope has a leak, fluid, biologic materials, and biofilm can collect in areas that cannot be adequately cleaned and disinfected."

END OF E-MAIL

The VA committee representative acknowledged receipt of this e-mail and stated that it would be distributed to all committee members.

VA management was aware of most of these pre-2007 deficits, as evidenced by the ENT-related pages from a 2007 memo from the Quality Management Coordinator. (Attachment CC)

To summarize, for most of 13 years, the ENT clinic's endoscope reprocessing was deficient in almost every way imaginable. This would necessarily mean that the rigid endoscopes posed a cross contamination hazard as well as the flexible ones. I am shocked that the VA's investigative committee should say that I told them that endoscope reprocessing was satisfactory except for leak testing prior to 2008. They appear disingenuous.

About 4,000 appointments per year were conducted in the ENT Clinic. (See the attached workload spreadsheet, Attachment DD) Additionally, ENT endoscopes were used in the Operating Room and the ER and were carried throughout the Medical Center for use on inpatients. They were even on occasion carried across the street for use at Washington Hospital Center! Over a 13 year period, the number of patients exposed to improperly disinfected endoscopes is very large. We can say that if the ENT Clinic conducted about 4,000 patients per year then 52,000 appointments clinic appointments were conducted in 13 years and that 75% or so of those appointments involved the use of a flexible or rigid endoscope.. To that number, we would have to add patients seen with ENT problems in the ER and the OR, as well as inpatients with ENT consultations. The number of veteran exposures to improperly disinfected ENT endoscopes is therefore staggering. Furthermore, the ENT endoscopes may possibly represent just the tip of and iceberg, for it would certainly be interesting to see the non-ENT pages of that 2007 Quality Management Coordinator's memo (Attachment CC)..

The risk of adverse health effects to veterans is serious. Suffice it to say that if one improperly disinfected endoscope can infect 9 patients in a two-and-a-half week period, then the ramifications of 52,000-plus patient appointments conducted with improperly disinfected endoscopes are obvious. For a knowledgeable person to believe that veterans were likely not cross contaminated with disease in such circumstances would be something like adult believing in the Tooth Fairy.

In an APICE study, Lawrence Muscarella, Ph.D. warned that "[Flexible laryngoscopes] have been reported to be contaminated with blood, body fluids, organic debris, and potentially pathogenic microorganisms during routine clinical use. Failure to reprocess properly a flexible laryngoscope may, therefore, result in patient-to-patient disease transmission" Helicobacter pylori, pseudomonas aeruginosa, enterobacteriaceae, mycobacterium tuberculosis, fungi, Hepatitis B, bacillius sp., seratia marcescens, fungus, and legionella pneumophila have all been documented to be transmitted by upper endoscopy endoscopes according to the Public Health Agency of Canada. That Agency goes on to postulate that even CJD may be transmitted if the tonsils are traumatized by endoscope insertion. There is concern that HIV may be transmitted. Common sense tells us that if an organism is present in blood, lymph or sputum, then it can be transmitted by being trapped inside an endoscope which has a hole in it! If you admit that, then transmittable diseases would include the common cold, flu, HPV (which is associated with 30 %

to 60% of all tracheolaryngeal cancers), and HIV. The 20011 Multisociety Guideline on Reprocessing Flexible GI Endoscopes remarks, "A Taiwanese case of Acinetobacter prosthetic valve endocarditis after polymicrobial bacteremia was, in the absence of other apparent sources, attributed to upper endoscopy performed 11 days earlier for esophagitis with associated esophageal ulceration.... Several occurrences of hepatitis C virus transmission have been associated with breaches in accepted endoscope reprocessing protocols.19-21 Most recently, lapses in the use of appropriate tubing with attached 1-way valves and lapses in reprocessing of the tubing used to attach water pumps to endoscope irrigation channels have been recognized in numerous centers around the United States, including several Veterans Administration hospitals."

I am aghast! In the face of overwhelming evidence of a danger to veterans' health, the VA investigators have dismissed the infection risks of failure to leak test, stating that the real purpose of leak testing is to prevent damage to the endoscopes. They have falsely stated that I told them that reprocessing was within standard-of-practice except for the matter of leak testing. And they did not even mention my report to them during their investigation that I have seen flexible endoscopes in the Medical Center as recently as 2015 which are not documented in the Medical Center's Equipment Inventory List and have no record of use or disinfection or even if they have been leak tested to date. (See Attachment EE.) Veterans deserve better!!! If they got sick, or remain sick, or even if they died of infectious disease of unknown source -- they (or their surviving families) deserve to be advised of this exposure and deserve to be offered follow-up testing!!! They have given so much for their country that they deserve for us to honor them with full disclosure and follow up testing!!! That is what I want. It is all I want. It is right, and just, and morally necessary!!.

That is my comment about the report of the VA's Office of the Medical Inspector.

Sincerely,

John Leahy, Staff RN
Silver Clinics
VAMC-DC

C C

Attachment B

VHA 2007 SPD HFMEA Topic Coversheet

Please submit this completed Coversheet along with the HFMEA forms by COB March 2, 2007.

VISN #: 5

Station #: 688

Facility Name: V.A. Medical Center, Washington, D.C.

Contact (name and phone number): Monica Rupp, RN, Quality Management Coordinator (202) 745-8000, ext 7441

Assigned Topic (number): 6

Identify all actions and their associated system vulnerabilities identified.

HFMEA Worksheet Page Number	Vulnerability	Action
1	1.A.2 Endoscope may not be used in examination room	• Provided biohazard bags inside transport case to cover contaminated endoscope from inpatient units after use.
2	2.A.1 Personnel without validated DC VAMC competency initiate the high-level disinfection process.	• ENT Clinic Staff, ENT Medical Staff, and rotating ENT Resident rosters and competencies will be reviewed and validated by 3/15/07. If no competency is identified, inservice training will be scheduled. • Inservice training for ENT Clinic Staff to be scheduled and provided by 3/31/07. • ENT Clinic Staff competencies to be validated and documented by 4/30/07. • Inservice training for Physicians and Residents to be scheduled and provided by 3/31/07. • Staff, ENT MD, and rotating resident competencies to be validated and documented by 4/30/07. • Quarterly audits for staff competency will be conducted by QM. First quarterly audit to occur by 5/31/07. • Quarterly performance spot checks will be conducted by QM. First quarterly audit to occur by 5/31/07.

CC

HFMEA Worksheet Page Number	Vulnerability	Action
3	2.B.1 Written protocol is not available for reference.	• Infection Control's "*Disinfection of Equipment Using Cidex OPA*" policy and competency were reviewed by 1/30/07. • ENT Clinic's *"Cleaning and High-Level Disinfection of Rigid, Non-lumen Endoscope"* protocol was reviewed and revised by 2/16/07. • Revised ENT Clinic protocol is to be sent to Clinical Practice Committee for review by 3/31/07. • Updated, approved ENT Clinic protocol is to be sent to Quality Management for production by Medical Media by 4/15/07. • Updated ENT Clinic protocol is to be posted in ENT Clinic Workroom by 4/30/07. • Quarterly spot check for posted ENT Clinic protocol will be conducted by Quality Management. First quarterly audit will occur by 5/31/07.
4	3.C.1 No stopclock/timer to identify when soaking (enzymatic detergent) began and should end.	• Timer was purchased 1/10/07, put into use by 1/15/07.
5	5.A.1 No stopclock / timer to identify when soaking (Cidex OPA) began and should end.	• Timer was purchased 1/10/7, put into use by 1/15/07.
6	5.A.4 Solution may not be tested for potency according to DC VAMC policy.	• Wall clock is to be hung by 2/23/07 to time 90 second Cidex OPA exposure to test strips.

CC

Please answer the following questions:

1. What were the most important/significant findings that should be shared?

- High-level disinfection is different than sterilization. Sterilization will destroy all microorganisms, including large numbers of resistant bacterial spores. High-level disinfection eliminates nearly all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g. bacterial spores) on inanimate objects.*
- Timers are essential to validate appropriate exposure times to enzymatic detergent and high-level disinfectant.
- Test strips needed to be used to test the potency of Cidex OPA (ortho-phthaldehyde) before each use. A clock is essential to validate appropriate exposure times of the test strip to Cidex OPA.
- ENT Clinic Scope High-Level Disinfection protocol needed to be reviewed, updated, disseminated, posted, and compliance audited quarterly.
- Staff, Attending ENT MD, and rotating ENT resident competencies needed to be reviewed, validated, documented, and audited quarterly.
- Since endoscopic exams are done for inpatients when the ENT Clinic is closed, biohazard bags were needed to cover contaminated scopes after use on the inpatient units.

2. What changes were made in the SPD process as a result of this HFMEA?

- The ENT Clinic protocol "*ENT Clinic Cleaning and High-Level Disinfection of Rigid, Non-lumen Endoscopes*" was reviewed and updated according to DC VAMC Infection Control's "*Disinfection of Equipment Using Cidex OPA*" policy and manufacturers' recommendations from Olympus (endoscope), Ruhof (enzymatic detergent) and Advanced Sterilization Products (Cidex OPA high-level disinfectant).
- The practice of enclosing a biohazard bag in the endoscope transport suitcase was initiated for use for covering the contaminated endoscope after inpatient use.
- The practice of using fresh enzymatic detergent each time an endoscope is cleaned was identified and incorporated into the ENT Clinic protocol.
- The practice of Cidex OPA potency testing prior to each use was identified and incorporated into the ENT Clinic protocol.
- A clock with a second hand was placed in the work room to time Cidex OPA exposure to test strips.
- Two timers were purchased to time endoscope exposure to enzymatic detergent and Cidex OPA.
- Signage indicating the revised processing steps will to be posted in the ENT Clinic workroom.
- Signage indicating that used endoscopes must be placed in biohazard bags will be posted in the examination rooms and on the outside of the endoscope transportation case.
- Labeling "Clean Endosocope" on storage cabinets in examination rooms is scheduled to occur.

CC

3. Other observations:

- Competencies for ENT Clinic staff, attending ENT MD, and rotating ENT residents are to be reviewed, and will be updated and audited to ensure continued competency and adherence to Infection Control's "*Disinfection of Equipment Using Cidex OPA*" policy and ENT Clinic's "*Cleaning and High-level Disinfection of Rigid, Non-lumen Endoscopes*".
- Inservice training for rigid endoscope processing and high level disinfection will be provided to ENT clinic staff, ENT MDs, and rotating ENT residents.

*Source: Block, Seymour S., Disinfection, Sterilization, and Preservation, 5th edition, 2001.

D 1)

WORKLOAD FOR ENT CLINICS
FOR 1 YEAR PERIODS ENDING 10/31

CLINIC	2008	2009	2010	2011	2012 PART
ENT	3659	3101	3182	2865	3065
ENT RSTR	87	456	329	459	868
OTOLOGY	0	0	95	101	89
C&P	347	476	546	368	169
TOTAL	4093	4033	4152	3793	4191

TOTAL ENT

EE

From: "Leahy, John C." <John.Leahy@va.gov>
To: "Jeanice, Trini" <Trini.Jeanice@va.gov>
Sent: Friday, June 5, 2015 9:37 AM
Subject: Undocumented flexible non-lumen endoscopes in Medical Center

For your information and that of the other Team members, this past week my supervisor called me to her office where she was waiting with a Biomed rep. Someone in the Medical Center had brought 2 endoscopes to Biomed. Whether this was for repair or other reason, I do not know. The problem was that Biomed could not remember whom they belonged to. There was no record of the scopes in the Sharepoint based high level disinfection system or even in the Medical Center's Equipment Inventory List. The Biomed rep and my supervisor asked for me to look at the scopes and tell them what I could. I told them that the two scopes were Olympus ENF Type V Visera rhino-laryngo videoscopes, non-lumen endoscopes – not to be confused with the PEF Type V TNE scope. They were older scopes, probably procured in the 1990's. I did not know who in the Medical Center owned them. They asked me if the ENT Clinic could use them. I told them that the ENT Clinic did indeed own a compatible equipment tower, but it already owned one ENF Type V, and probably would not want these two. I suggested that Biomed contact Olympus with the serial numbers and trace who had purchased them.

The take-away point here is that here are 2 ageing non-lumen flexible endoscopes in the Medical Center of which there is no record of use, disinfection, or leak testing. Why are they not in the Equipment Inventory List? Where were they used? How were they disinfected? Have they even been leak tested to this date???? These questions have such a direct bearing on my complaint that I just had to let you know.

Thank you.

John Leahy

RN, BSN, MA

VA Medical Center, DC

From: Jeanice, Trini
Sent: Thursday, March 19, 2015 2:42 PM
To: Leahy, John C.
Subject: RE: Follow up today's meeting

Thank you Sir,

Will forward to the other team members.

V/r

Trini

Trini L. Jeanice, RN, MSN, FNP

Clinical Program Manager

Office of the Medical Inspector

Veterans Health Administration

810 Vermont Ave, NW

Washington, DC 20420

202-443-5094

202-679-7808 (BB)

202-495-6200 (Fax)

From: Leahy, John C.
Sent: Thursday, March 19, 2015 2:13 PM
To: Jeanice, Trini
Subject: Follow up today's meeting

Follow up to today's meeting with the inspection team:

I am writing to make sure I have clearly communicated the information you requested today. As I said, I personally believe that the lack of leak testing prior to 2008 was the most significant issue endoscope disinfection. Just to be clear, other problems included (1) before 2007 lack of timers for timing of cidex opa soak times, (2) before 2007 lack of a written sop, (3) before 2007 lack of a wall clock for timing of cidex test trip quality checks, (4) before 2008 use of MAJ-210 biopsy port covers on the PEF Type V scope (5) before 2008 lack of suction equipment, (6) before 2008 lack of leak testing equipment, (7) before 2008 lack of power outlets to support suction or leak testing, (8) before 2008 lack of temperature testing for cidex opa, and (9) lack of bioburden testing for the PEF Type V scope, (10) before 2008 lack of a MAJ-1219 cleaning adapter for the PEF Type V scope.

Regarding the infection risk inherent specifically in leaking endoscopes, here is one source of many:

http://www.psa.edu.my/cmet/publications/Digest/ENDOSCOPE%20LEAKAGE%20TESTER.pdf

"Infection Control Considerations

From an infection control perspective, proper leak testing is one of the most crucial and vital steps. Cross-infection is a risk if a leak is left unchecked. Retained organic soil can inactivate germicides. It can also prevent contact of the germicide with potentially contaminated surfaces. Both circumstances create an infection risk. If a scope has a leak, fluid, biologic materials, and biofilm can collect in areas that cannot be adequately cleaned and disinfected."

John Leahy, RN, BSN, MA

Silver Clinics (First Floor)

Department of Veterans Affairs Medical Center, Mail Stop 112

50 Irving Street, NW

Washington, DC 20422

Tel. 202-745-8000 ext. 7408

FAX 202-745-8293

8 PAGES ATTACHMENT AA
SEE MARKED PORTION

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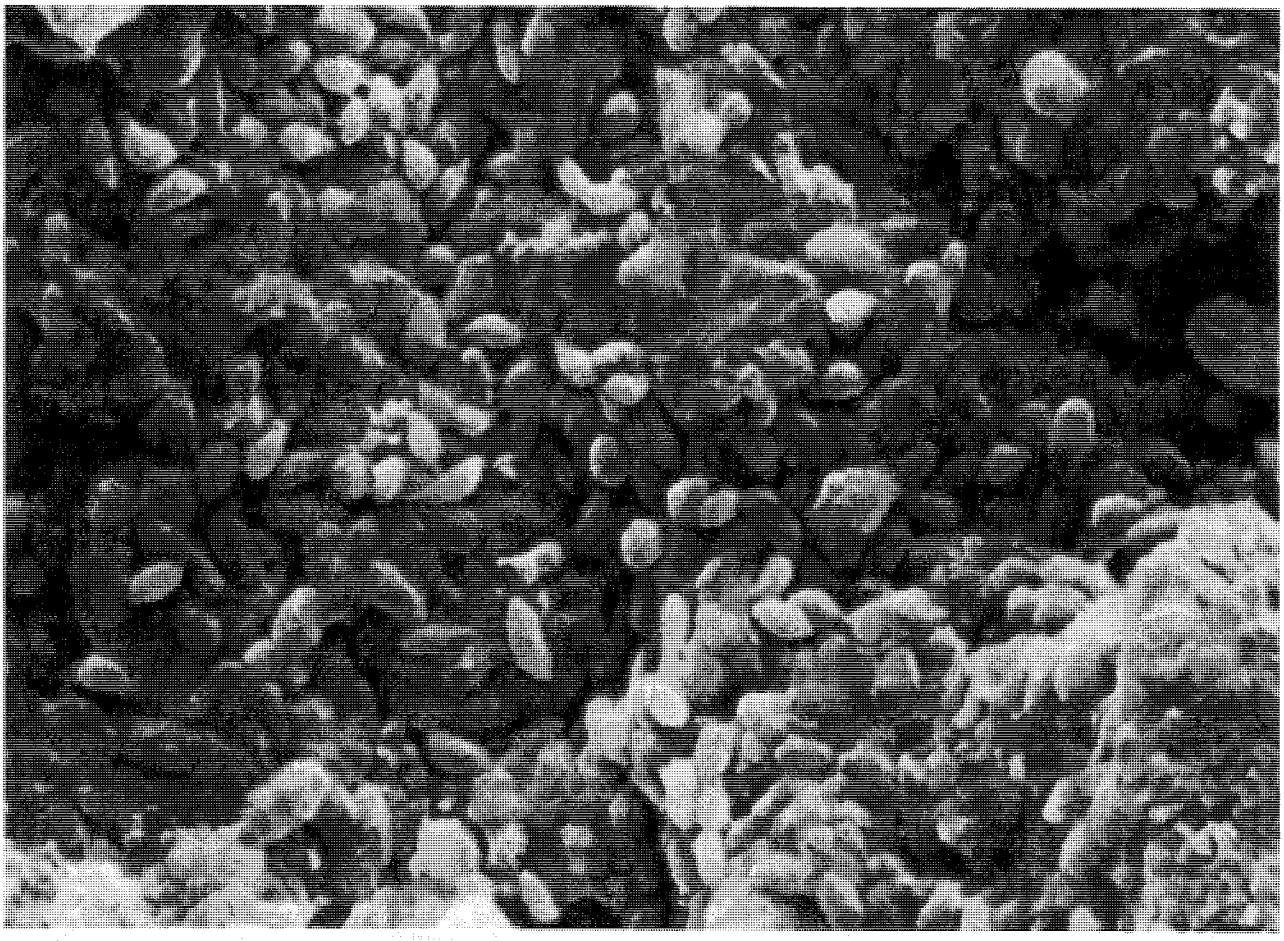
Ideas that work for life

Bronchoscopy-Related Cross-Contamination
The problem and the solution



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A A

Bronchoscopy-Related Cross-Contamination
– Difficult to resolve with reusable bronchoscopes

- Decontamination of reusable bronchoscopes is laborious, time-consuming and requires meticulous attention to detail[2]
- Endoscope reprocessors must be compatible with the corresponding type of bronchoscope[1,2]
- Procedures for manual cleaning and disinfection of bronchoscopes may not always be adhered to[2]
- Bronchoscopes must be inspected for surface damage and leak-tested after each procedure[3]

Flow chart for endoscope reprocessing:

Single-use bronchoscopes do not require disinfection, manual cleaning or leak testing

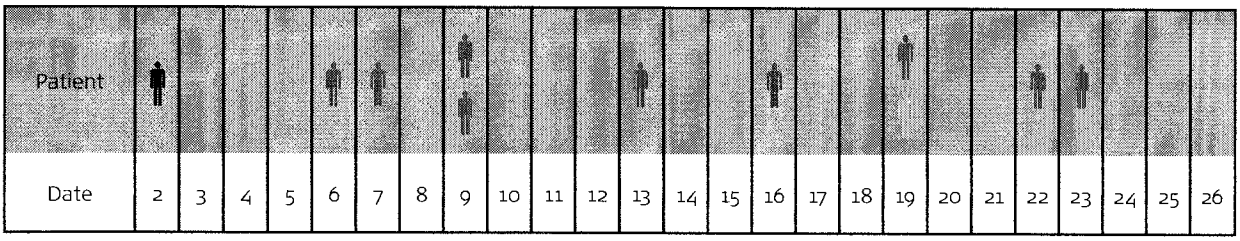
1. Culver DA et al. Am J Respir Crit Care Med 2003, 167:1050-1056
2. Larson JL et al. Infection Control and Hospital Epidemiology 2003; 24(11):825-830
3. Ramsey AH et al. Chest 2002 121(3):976-979

A A

Lack of Bronchoscope Leak-Testing

– 9 patients were Cross-Contaminated with TB over a two and a half week period[3]

Bronchoscopic procedures performed during July 1999 using the same instrument[3]



Modified with permission from the American College of Chest Physicians. An outbreak of bronchoscopy-related Mycobacterium tuberculosis infections due to lack of bronchoscope leak testing. Ramsey AH et al., Chest. 2002 Mar;121(3):976-81.

= Bronchoscopic procedure on infected patient

= Bronchoscopic procedures where tuberculosis culture was found

= Bronchoscopic procedure where culture was found but not identified

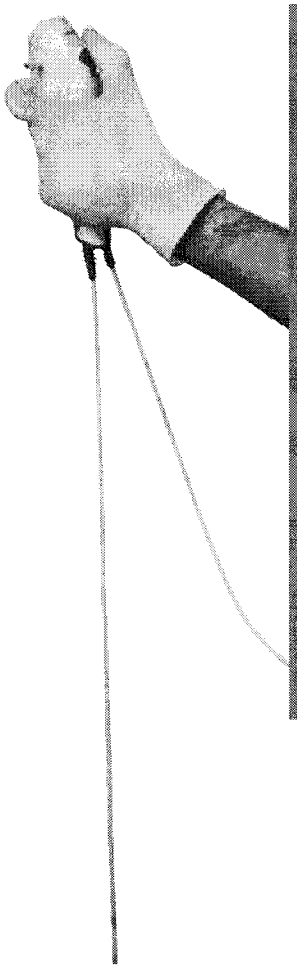
- 10 patients tested positive TB[3]
- All patients underwent bronchoscopy with the same scope[3]
- All cultures had identical DNA pattern indicating a common origin[3]
- The bronchoscope had a hole in the distal sheath[3] where infected material accumulated
- Leak testing was not performed as part of the reprocessing procedures[3]

With single use bronchoscopes there is no risk of Cross-Contamination

3. Ramsey AH et al. Chest 2002 121(3):976-979

A A

Ambu® aScope™
– a unique, single-use solution



- The single-use concept of aScope™ eliminates the risk of bronchoscope based Cross-Contamination
- With the aScope™ there is always a scope at hand when needed
- aScope™ is a unique alternative to eliminate the laborious, time consuming and error-prone disinfection process.
- With its low acquisition costs and no cleaning and repair costs, it is an ideal solution for the OR, ER and ICU

BB

Leahy, John C.

From: Jeanice, Trini
Sent: Thursday, March 19, 2015 2:42 PM
To: Leahy, John C.
Subject: RE: Follow up today's meeting

Thank you Sir,
Will forward to the other team members.
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Trini

Trini L. Jeanice, RN, MSN, FNP
Clinical Program Manager
Office of the Medical Inspector
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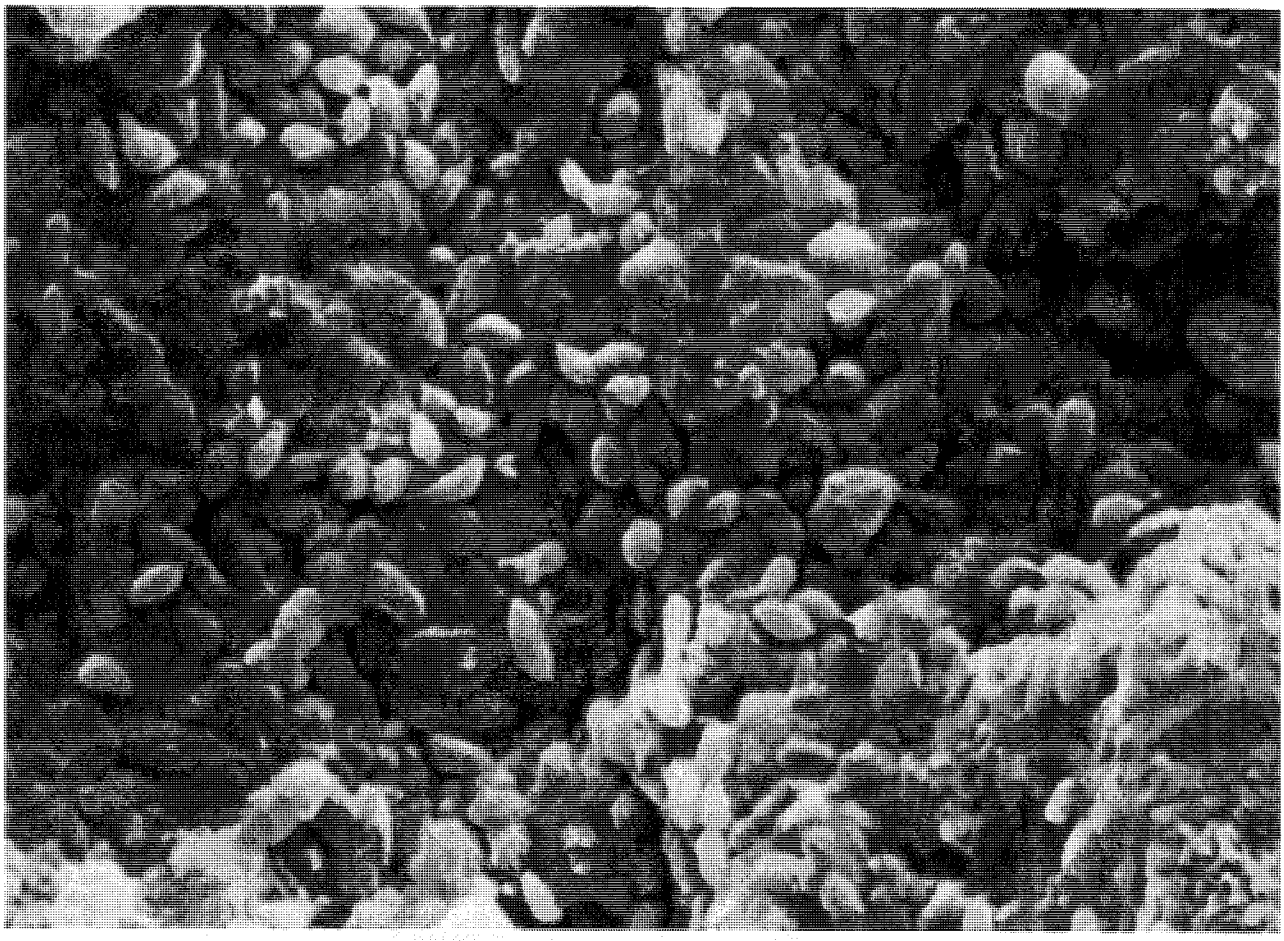

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A A

Bronchoscopy-Related Cross-Contamination – a Genuine Threat

- More than 59 published articles reporting almost 1000 patients Cross-Contaminated by reusable endoscopes[1]
- At least 3 deaths are documented[1] directly related to Bronchoscopy-Related Cross-Contamination
- Most cases are described as pseudo-infections with no clinical evidence of infection[1]
- A common pathogen reported is mycobacterium tuberculosis (TB)[1]
- Because of lack of prospective studies of pathogen transmission, the actual incidence is unknown and likely under-reported[1]

"Under-recognition and under-reporting of bronchoscopic pathogen transmission has contributed to a sense of complacency regarding infection control in the bronchoscopy suite"

1. Culver DA et al. Am J Respir Crit Care Med 2003, 167:1050-1056

A A

Bronchoscopy-Related Cross-Contamination – Difficult to resolve with reusable bronchoscopes

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Flow chart for endoscope reprocessing:

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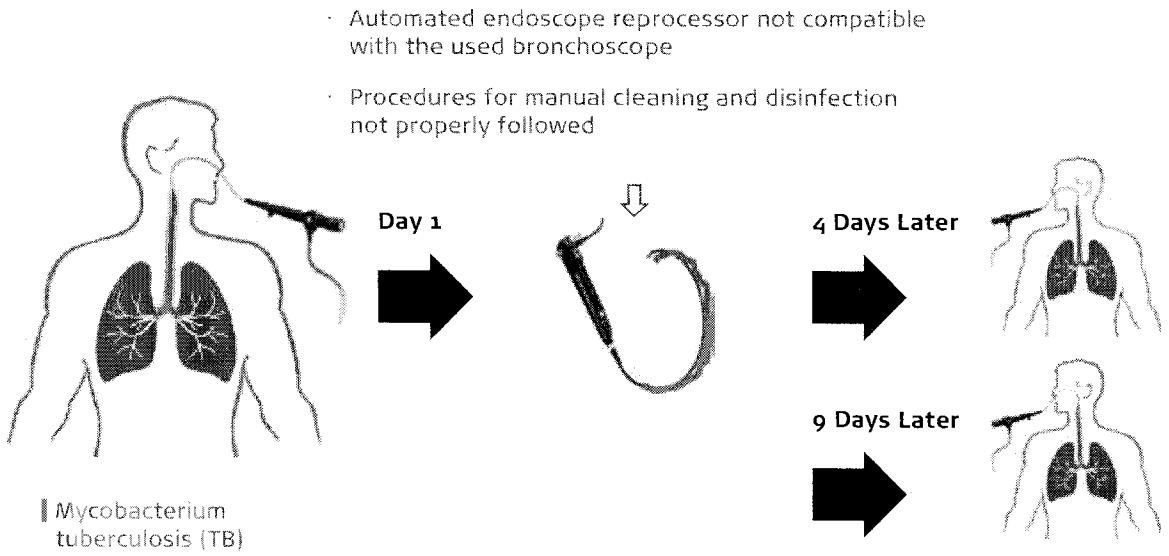
1. Culver DA et al. Am J Respir Crit Care Med 2003, 167:1050-1056
2. Larson JL et al. Infection Control and Hospital Epidemiology 2003; 24(11):825-830
3. Ramsey AH et al. Chest 2002 121(3):976-979

A A

Example of incompatible endoscope reprocessing – 2 patients Cross-Contaminated with TB[2]



- Positive TB cultures originating from the same bronchoscope[2] were verified
- Origin of contamination verified by DNA fingerprint analysis eliminating other possible sources[2]
- Patient debris were found on the suction connector due to poor compliance with cleaning procedures[2]
- The bronchoscope used was not compatible with the reprocessor system[2]

Single-use bronchoscopes do not require scope-compatible reprocessing equipment

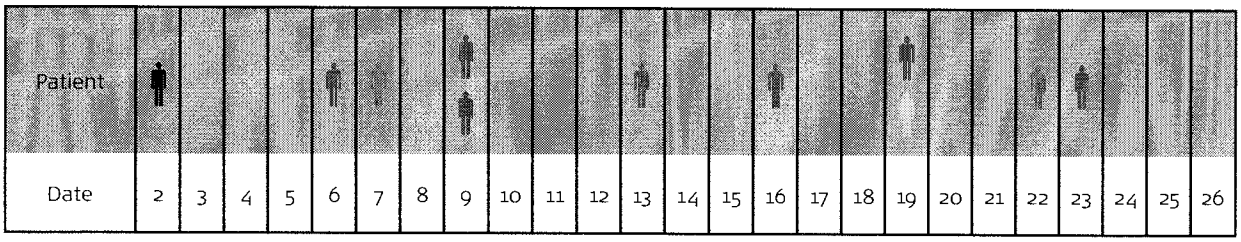
2. Larson JL et al. Infection Control and Hospital Epidemiology 2003; 24(11):825-830

A A

Lack of Bronchoscope Leak-Testing

– 9 patients were Cross-Contaminated with TB over a two and a half week period[3]

Bronchoscopic procedures performed during July 1999 using the same instrument[3]



Modified with permission from the American College of Chest Physicians. An outbreak of bronchoscopy-related Mycobacterium tuberculosis infections due to lack of bronchoscope leak testing. Ramsey AH et al., Chest. 2002 Mar;121(3):976-81.

= Bronchoscopic procedure on infected patient

= Bronchoscopic procedures where tuberculosis culture was found

= Bronchoscopic procedure where culture was found but not identified

- 10 patients tested positive TB[3]
- All patients underwent bronchoscopy with the same scope[3]
- All cultures had identical DNA pattern indicating a common origin[3]
- The bronchoscope had a hole in the distal sheath[3] where infected material accumulated
- Leak testing was not performed as part of the reprocessing procedures[3]

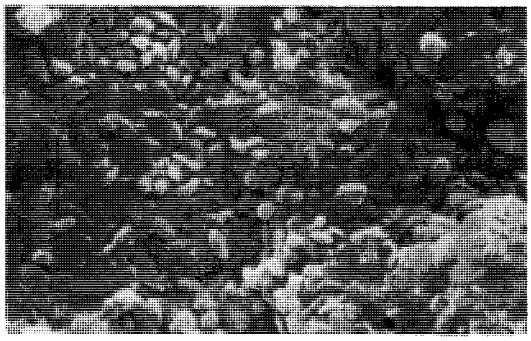
With single use bronchoscopes there is no risk of Cross-Contamination

3. Ramsey AH et al. Chest 2002 121(3):976-979

AA

Poor Cleaning of Persistent Biofilm
– failure of decontamination due to formation of biofilm

Suction channel with surface defects and associated biological soil and microorganisms



Air/water channels with biofilm

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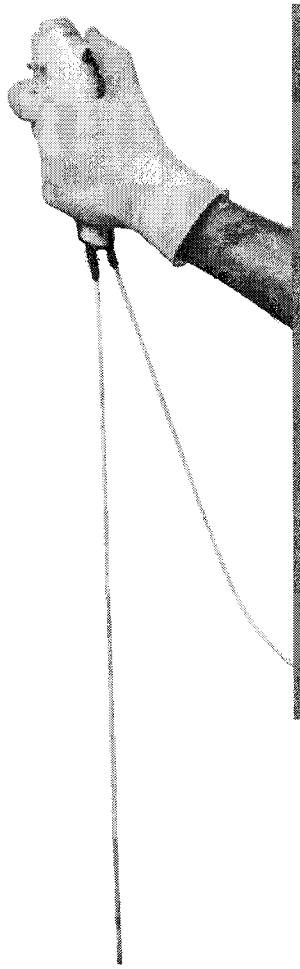
- Biofilm consists on the accumulation of bacterial or fungal cell clusters[4]
- Biofilm is more resistant to chemical inactivation than bacteria in suspension is[4]
- Biofilm was identified in 13 of 13 endoscopes despite appropriate cleaning procedures being followed[4]
- Biofilm was present in the channels of 12/13 instruments
- Routine cleaning does not effectively remove biofilm from endoscope channels[4]

Single-use bronchoscopes do not house accumulation of biofilm

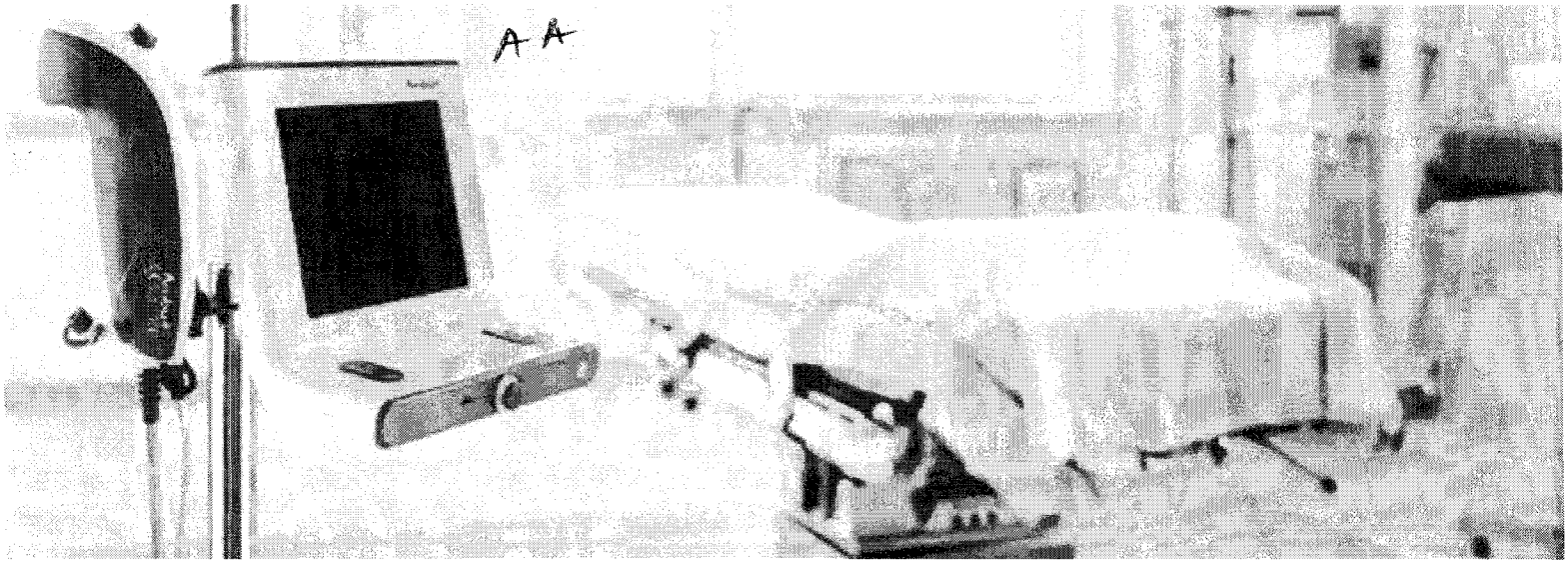
4. Pajkos A et al. Journal of hospital infection 2004; 58:224-229

A A

Ambu® aScope™
– a unique, single-use solution



- The single-use concept of aScope™ eliminates the risk of bronchoscope based Cross-Contamination
- With the aScope™ there is always a scope at hand when needed
- aScope™ is a unique alternative to eliminate the laborious, time consuming and error-prone disinfection process.
- With its low acquisition costs and no cleaning and repair costs, it is an ideal solution for the OR, ER and ICU

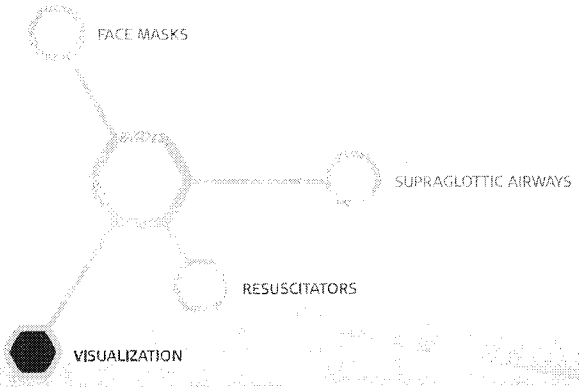


A higher level of practicality

The single-use concept combined with its user-friendly, lightweight design and new camera technology makes the aScope™ a unique alternative to reusable scopes. After use, it can be discarded as with any other disposables used. In short, the Ambu® aScope™ provides greater convenience for everyone involved.

Eliminating the risk of Cross-Contamination

Flexible scopes are difficult to clean and disinfect. Guidelines and recommendations should be strictly followed, but are time consuming and costly[1, 2, 3]. And, despite guidelines being followed, it is impossible to avoid the accumulation of biofilm in the narrow channels and surface imperfections. With the increasing risk of resistant bacterial strains, the need for new and smarter solutions such as the aScope™ is evident.



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BB

Leahy, John C.

From: Jeanice, Trini
Sent: Thursday, March 19, 2015 2:42 PM
To: Leahy, John C.
Subject: RE: Follow up today's meeting

Thank you Sir,
Will forward to the other team members.
V/r
Trini

Trini L. Jeanice, RN, MSN, FNP
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Office of the Medical Inspector
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202-443-5094
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202-495-6200 (Fax)

From: Leahy, John C.
Sent: Thursday, March 19, 2015 2:13 PM
To: Jeanice, Trini
Subject: Follow up today's meeting

Follow up to today's meeting with the inspection team:

I am writing to make sure I have clearly communicated the information you requested today. As I said, I personally believe that the lack of leak testing prior to 2008 was the most significant issue endoscope disinfection. Just to be clear, other problems included (1) before 2007 lack of timers for timing of cidex opa soak times, (2) before 2007 lack of a written sop, (3) before 2007 lack of a wall clock for timing of cidex test trip quality checks, (4) before 2008 use of MAJ-210 biopsy port covers on the PEF Type V scope (5) before 2008 lack of suction equipment, (6) before 2008 lack of leak testing equipment, (7) before 2008 lack of power outlets to support suction or leak testing, (8) before 2008 lack of temperature testing for cidex opa, and (9) lack of bioburden testing for the PEF Type V scope, (10) before 2008 lack of a MAJ-1219 cleaning adapter for the PEF Type V scope.

Regarding the infection risk inherent specifically in leaking endoscopes, here is one source of many:
http://www.psa.edu.my/cmet/publications/Digest/ENDOSCOPE%20LEAKAGE%20TESTER.pdf

"Infection Control Considerations
From an infection control perspective, proper leak testing is one of the most crucial and vital steps. Cross-infection is a risk if a leak is left unchecked. Retained organic soil can inactivate germicides. It can also prevent contact of the germicide with potentially contaminated surfaces. Both circumstances create an infection risk. If a scope has a leak, fluid, biologic materials, and biofilm can collect in areas that cannot be adequately cleaned and disinfected."

.... PLEASE READ RESEARCH ENROLLMENT POSTING .....

<< OLE Object: Picture (Device Independent Bitmap) >>

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