Medical Device Reprocessing Challenges

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Webinar Presenters

Laurie Reed, Vice President, Research & Usability

Laurie manages the Research & Usability group at Farm, is a program manager, and a senior human factors engineer with over 15 years of experience. She is responsible for resourcing and overseeing all projects for the research and usability team, authoring proposals, managing research and usability staff members, and managing usability templates for Farm's quality system. She specializes in both formative and summative usability testing, and has experience in a wide range of other user research techniques including contextual interviews, anthropometric/ergonomic analyses, and product safety/hazard analyses. She's responsible for managing projects, designing and administering usability tests and other types of user research, conducting interviews, performing data analyses, recommending design refinements, and presenting results to clients. At Farm, Laurie has led and moderated several summative usability tests for regulatory submission, on various types of medical products. Laurie also specializes in recruiting participants for various user research studies across the U.S. and abroad. Laurie has worked for clients such as AcelRx, Medtronic, J&J LifeScan, Animas, Siemens, Gamma Medica, Ethicon Endo-Surgery, Smiths Medical, Philips Healthcare, GlaxoSmithKline, GE Life Sciences, Grove Instruments, MedlinePlus, National Library of Medicine, and NinePoint Medical. She holds a BA in human factors engineering from Tufts University. Prior to her current position, she was a research scientist at the American Institutes for Research (AIR). She also owned and operated her own research recruiting company for nine years.

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Cheryl Kwinn, Human Factors Engineer

Cheryl is a human factors engineer. Her interests are user research, contextual inquiry, and usability testing. She has experience moderating interviews, planning and conducting formative evaluations to inform design recommendations, conducting usability tests, supporting documentation development, and analyzing data. At Farm, Cheryl has recently moderated or supported multiple usability validation tests for FDA submission. Cheryl went to Tufts University to study for her Master of Science in Human Factors, and received a BS in Brain and Cognitive Sciences from the Massachusetts Institute of Technology. Before joining Farm, Cheryl was a graduate research assistant for Tufts University, where she led user research and usability testing for a medical decision support device at the Clinical and Translational Sciences Institute (CTSI) at Tufts Medical Center.

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Scope

This presentation intends to discuss the reprocessing of reusable medical devices in healthcare facilities. These reusable devices are used by health care providers to diagnose and/or treat multiple patients.

Examples of reusable devices that may be reprocessed:

- Surgical instruments (clamps, forceps)
- Scopes (bronchoscopes, duodenoscopes, colonoscopes)
- Laparoscopic instruments

This does not include reprocessing devices intended for single use.

Reprocessing

1 What is Reprocessing?

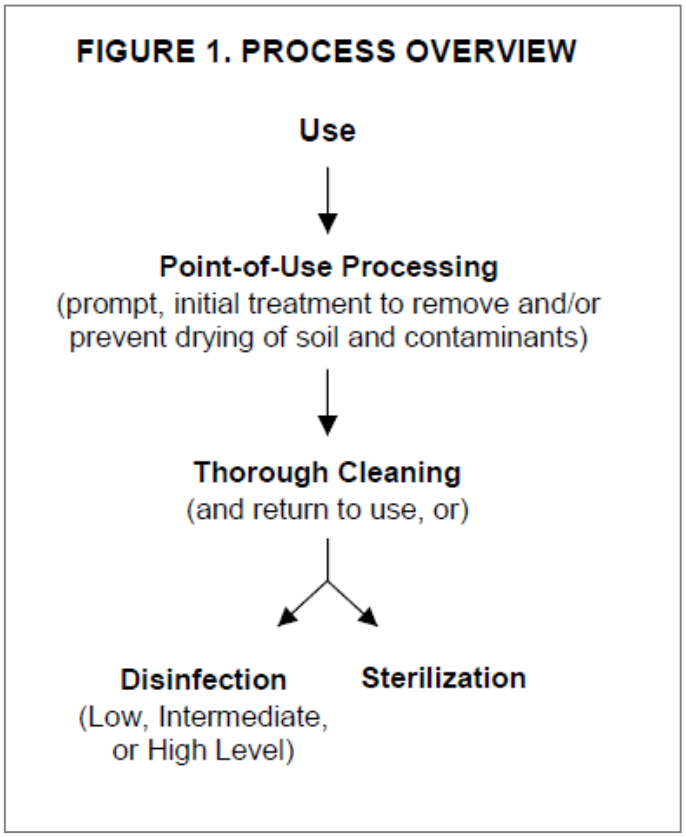
What is Reprocessing?

Reprocessing is a multi-step process including the cleaning, disinfection, sterilization and repackaging of a used medical device so that it can be put back in service again.

The goal of reprocessing is to remove contaminants such as microorganisms so that when the device is reused the risk of infection is eliminated.

Photo source www.montrealgazette.com

What is Reprocessing?



Source: fda.gov

Source: Biotest Laboratories

"Adequate reprocessing of reusable medical devices is vital to protecting patient safety." ~fda.gov

2

When Does Reprocessing Happen?

Where Does Reprocessing Happen?

Reprocessing of medical devices may happen in a variety of settings, including:

- Large health care facilities like hospitals
- Small inpatient and outpatient facilities
- Small medical office suites
- Stand alone provider facilities such as ambulatory surgery centers
- Stand alone reprocessing service facilities

Reprocessing facilities go by different names, but we will refer to them as Central Sterile or as CSSDs.

Photo source hpnonline.com

Where Does Reprocessing Happen?

The layout of CSSDs is fairly consistent:

1) Materials first enter the **dirty room** in the cleaning area

2) They are then passed into the **clean room** for drying, inspection, assembly, packaging, and sterilization, after which the materials are brought to the **storage and preparation** area.

Dirty Room

1) Cleaning Area

Clean Room

2) Drying Area

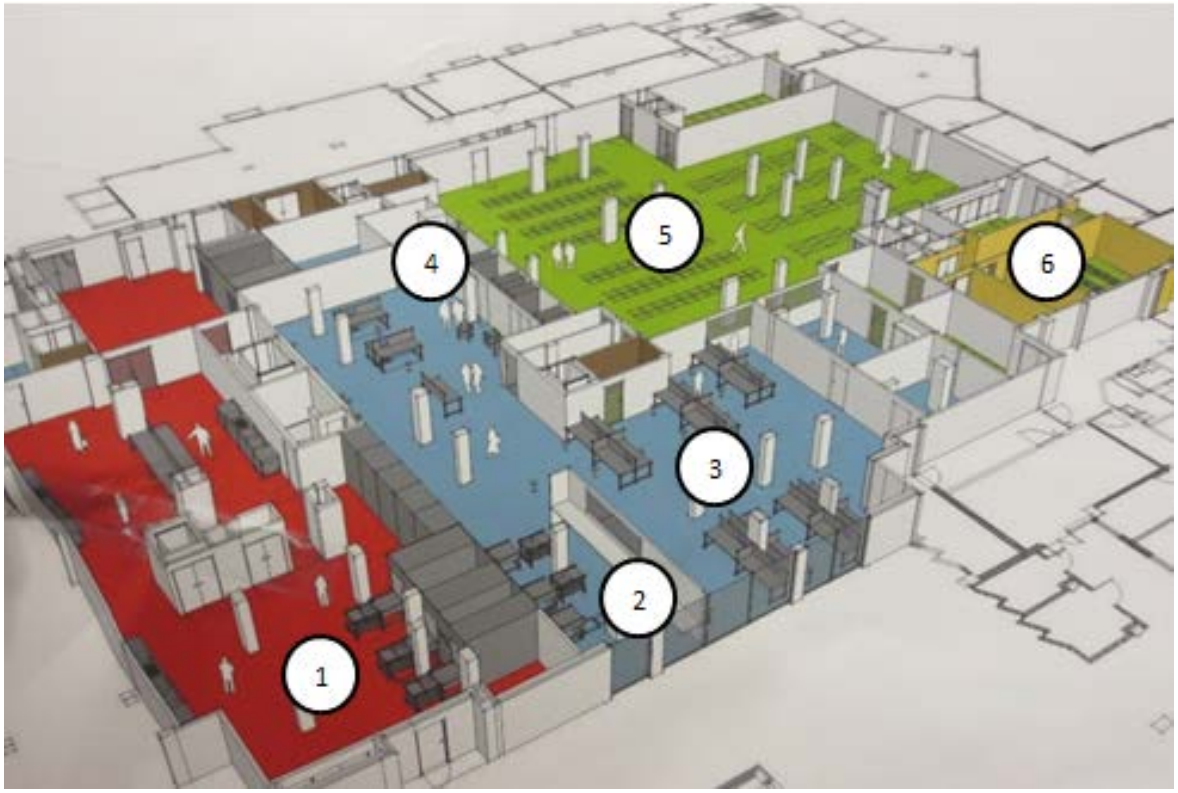
3) Inspection, Packaging, & Assembly Area

4) Sterilization Area

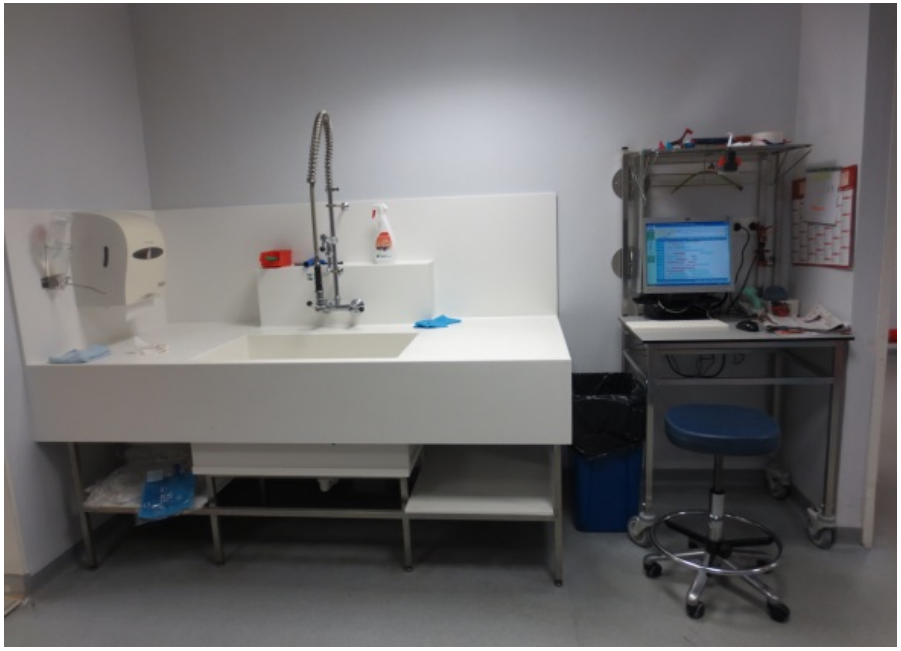
Other

5) Storage & Preparation Area

6) Administrative Area



Where Does Reprocessing Happen?



Cleaning Area

This is where the first steps (cleaning and/or disinfection) of reprocessing happen.

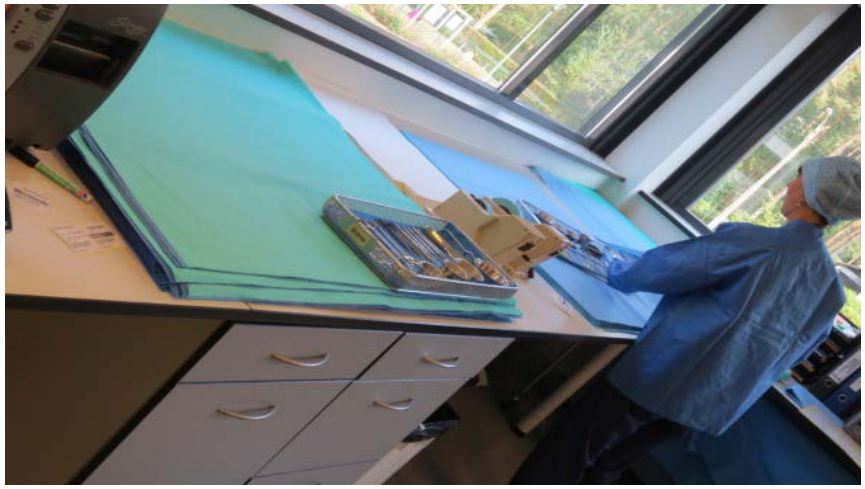
- Usually one person is responsible for the manual pre-cleaning process and then putting the instruments into the automatic washers/disinfectors (if the CSSD is using an automated cleaning process) or one person is responsible for the manual cleaning of the instruments and then putting the instruments into the ultrasonic bath.
- Other products may be disassembled here for cleaning and disinfection, to be reassembled on the clean side.

Where Does Reprocessing Happen?

Instruments are brought to the clean side through either the automatic washer/disinfector or through a vaulted pass-through.

Drying Area

This is where instruments are either brought out of the automatic washer/disinfectors after the appropriate dry time (dependent on cycle) or instruments/scopes are dried before packaging.



Inspection, Assembly, and Packaging Area

This area is for packaging the instruments and endoscopes before they are sterilized. One person is typically responsible for inspecting that the instruments and scopes are clean (and, if necessary, disinfected). In this area, instruments are packed (either in paper or in cartons) to be sterilized

Where Does Reprocessing Happen?

Sterilization Area

In the Sterilization Area, packed instruments and endoscopes are placed into the appropriate machine for sterilization. Sterilization machines include: autoclaves, Sterrad/Sterris, formaldehyde sterilization, among others.

Storage and Packaging Area

Once cleaned, disinfected, dried, assembled, validated, packaged, and sterilized, instruments and endoscopes are ready to be stored or prepped for distribution to the Operating Rooms.

Case Study – Understanding the Reprocessing Environment

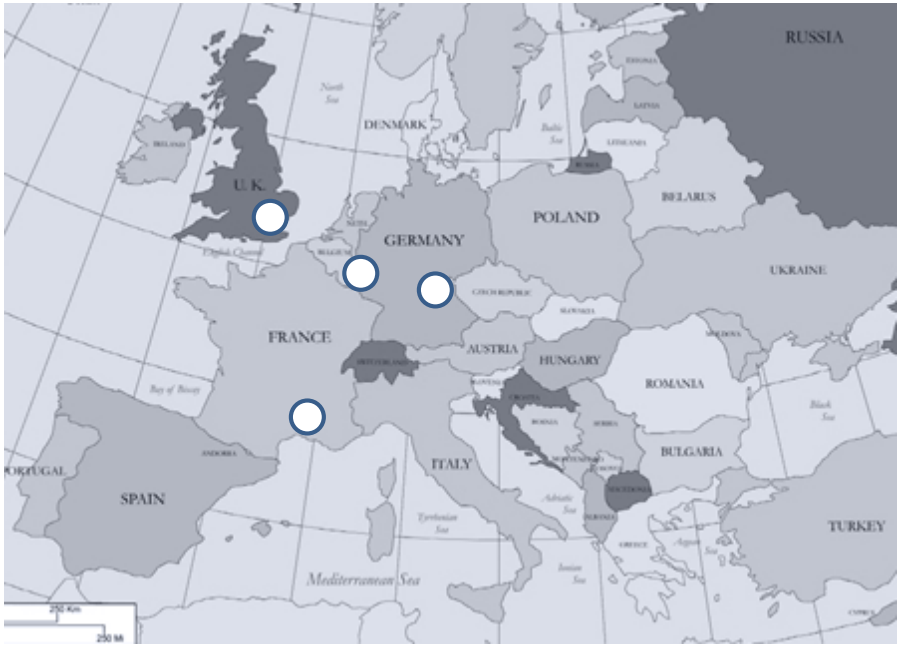
Study Overview

The purpose of the study was to:

- Gain an understanding of how surgical instruments make their way from the operating room through the CSSD at various hospitals.
- Document the CSSD use environment, noting any challenges, workarounds, use of reference documents and wall charts, etc.
- Take stock of the current reprocessing workflow, noting any issues, concerns, or major challenges.

The study was conducted:

- In September 2014.
- By a project team consisting of two Farm staff members and three client members.
- At 7 hospitals in four countries in Europe: Germany, France, Belgium, and the United Kingdom.



Study Overview

Methodology

- The team conducted sit-down interviews with the CSSD managers and other pertinent staff members.
- Following the interviews, the research team was given a tour of the CSSD.
- When possible, the project team observed as CSSD participants demonstrated the process of cleaning and sterilizing certain instruments.
- Team members asked additional interview questions, took hand written notes, and documented the use environment by taking photos.

Study Results: Workflow

- Pre-treatment or point-of-use processing does not always take place in the OR.
- Instruments make their way from the OR down to the CSSD. This may happen in a variety of ways and can take varying lengths of time.
- Instruments move their way through the CSSD zone by zone. Personnel are usually assigned to a specific zone and are either rotated through other areas throughout the day or throughout the week.
- Different individuals at a given facility may be responsible for cleaning, sterilization, assembly, packaging, and validation of the same surgical instrument.
- Performing manual vs. automatic reprocessing had an influence on the path of a given instrument and how long it would take to complete the process.

Photo source matot.com

Study Results: Equipment

- CSSDs were caught by surprise at the sudden arrival new instruments. Although they may have been aware that the hospital was purchasing new equipment, CSSDs were widely not included in the planning stages.
- Because of their lack of involvement in planning for new devices, the CSSDs didn't have all of the desired equipment to reprocess new instruments.
- Having to perform the manual process, as opposed to the automatic process resulted in concerns over time consumption and the domino effect it has on workload.
- The CSSDs didn't always have access to the indicated accessories or supplies that were referenced in the IFU.

Study Results: Instrument Complexity

Some CSSDs expressed concern over reprocessing new instruments that were deemed more complex than their predecessors.

They worried that:

- OR and CSSD staff would forget to perform certain steps.
- Complex instrument would cause increased drying time.
- CSSDs would not have the right sterilization and transportation trays or drying cabinets to fit bigger instruments.

The ability to disassemble instruments is highly preferred.

Photo source mdtmag.com

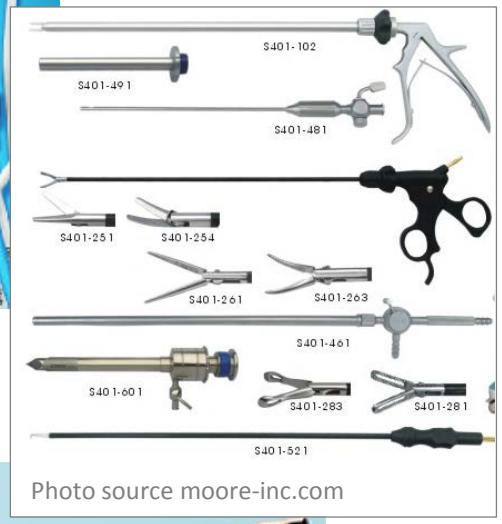


Photo source moore-inc.com

Photo source beeremedical.com

Study Results: Instrument Complexity

"I appreciate that this may be easier for the surgeon but I would like designs that are increasingly easier to reprocess, not harder."

"It would be difficult to do pre-treatment of [this instrument] due to its length."

"Why is this plastic? That doesn't dry very well even though it's good for cable management."

"There are too many ports. How easy is this going to be to flush with limited space and the angle at which you would have to place the syringe?"

"This [instrument] will not fit in our sink so I have to use a bin right now and I'm spending £4,000 on a new sink!"

"What if water were to get in the connector end? It would cause damage, especially if it was an evening surgery and it was left overnight to be reprocessed the next day."

Study Results: OR Pretreatment

Not all sites currently have their OR support staff pretreat reusable instruments at the point of use, and in some instances the staff are only doing one part of pretreatment. The CSSD staff, therefore, is responsible for cleaning any dried bioburden.

- *"No, the OR does nothing (…). They bring instruments straight to CSSD and we do everything in CSSD."*
- *"The OR staff has not received any training on pre-cleaning. They need to change procedures quickly, and therefore need to focus on the process in the theater. It's new to them on how to prep the instruments."*
- *"The OR is currently not doing flush because we are concerned about corrosion with liquid inside of the instruments… Instead, the instruments are kept in a prolonged enzymatic bath in the CSSD for as long as it takes to get clean."*

Photo source outpatientsurgery.net

Study Results: Delays in Reprocessing – Instrument Arrival to the CSSD

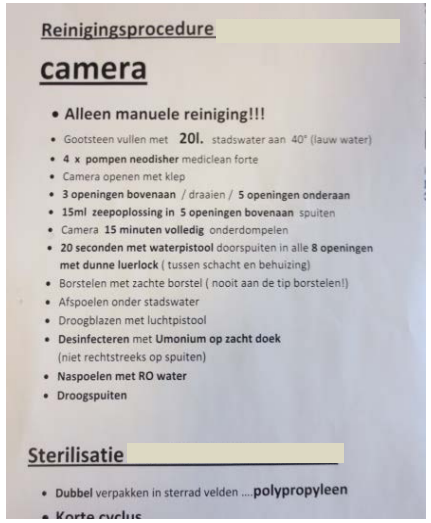
In some cases, the CSSD is located in convenient proximity to the operating suite. Complex instruments may even have a unique, special system for transporting to the CSSD to ensure that the instruments can be reprocessed right away.

However, for other hospitals, it can take anywhere from 60 minutes to over 24 hours for an instrument to arrive in the CSSD from the OR.

- Some sites are not able to reprocess complex instruments in their facility, and have to send out the instruments to remote CSSDs.
- Some hospitals require the CSSD staff to pick up the instruments from the OR, and so the instruments are only picked up on the regular pick-up schedule.
- Additionally, if a CSSD closes before the day's operations end, instruments may need to wait to be picked up the next morning.

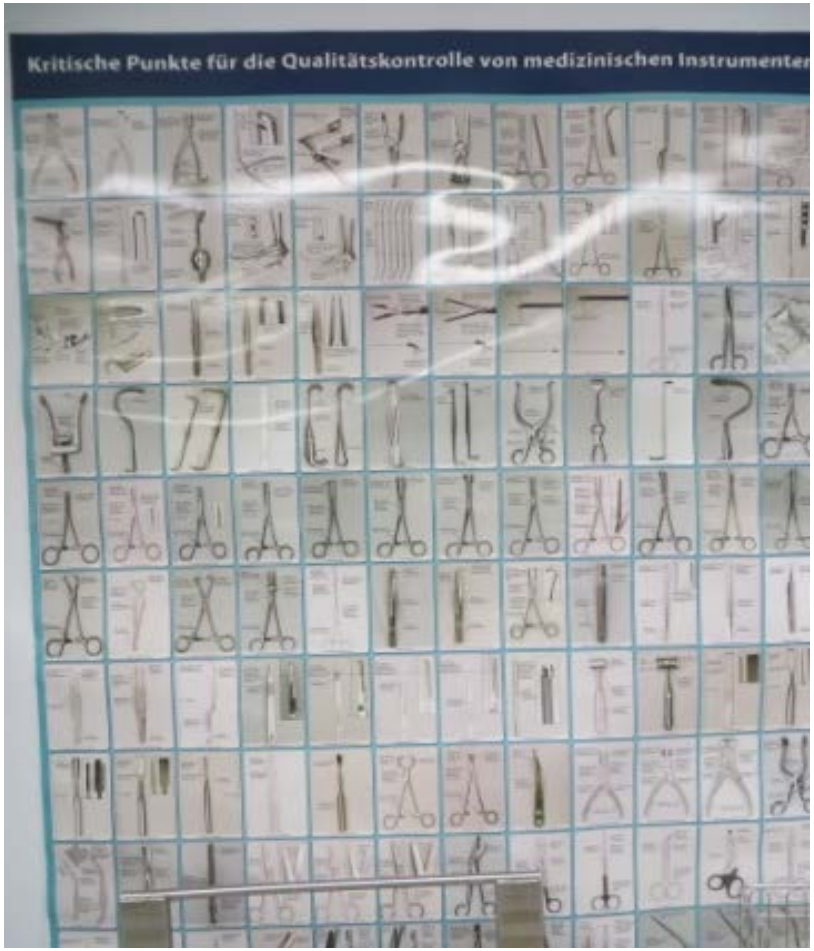
Study Results: Reference Materials

- Staff were generally not referring to manufacturers' reprocessing manuals during reprocessing.
- All sites use the manuals as an input to create their own SOPs. SOPs take into consideration:
  - The manuals' recommendations
  - Country-specific regulations
  - Hospital-specific policies
- Most sites had the manuals filed away and expressed the desire to be able to access the manuals electronically for easier integration into their system.



Study Results: Reference Materials

- Most sites indicated that they do not like to use wall charts.
  - Dust / concerns over environment
  - Revision validation by notified bodies
  - Excess number of wall charts
  - Not matching their specific SOPs
- Because of the zoned layout of the CSSDs, wall charts containing instructions that related to multiple zones were seen as unfavorable.
- Staff indicated they would be more likely to use wall charts that were laminated and contained helpful images.

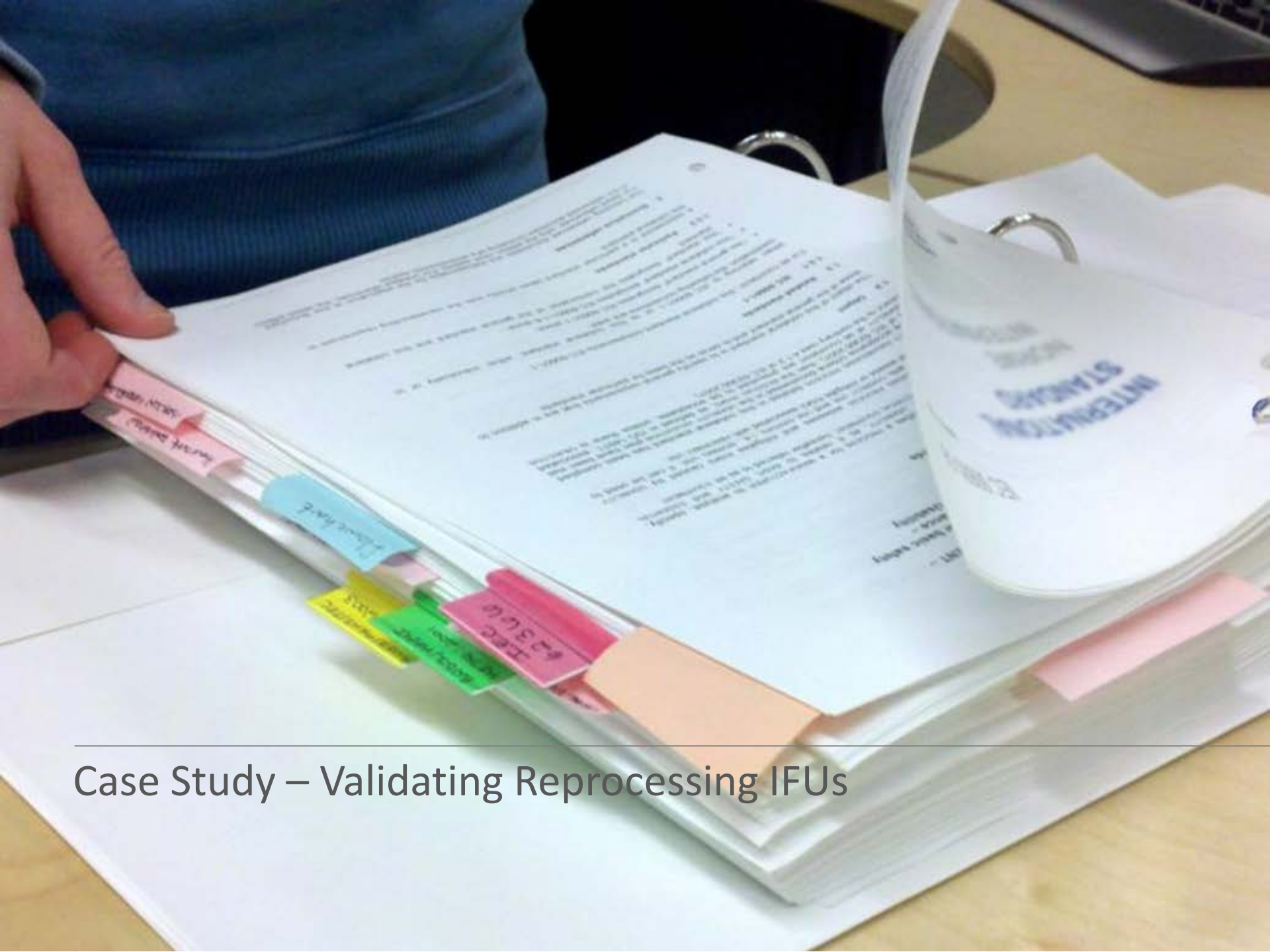


Study Results: Training

- CSSD is typically trained on how to reprocess a complex instrument by the manufacturer when the instrument arrives or is about to arrive.
- After the initial manufacturers training, however, training on reprocessing often happens in a variety of ways:
  - The CSSD manager may train the new staff member.
  - A trained colleague may train new staff members, often with shadowing or an apprenticeship/mentorship.
  - Often, the new staff member would be responsible for reading and using the manual when reprocessing. He would also have access to the electronic SOPs to remind themselves while reprocessing.
  - This new staff member would be responsible for learning how to reprocess all of the instrumentation used in the hospital, from the simple to the highly complex, through one or more of these methods.
- Sites requested a visual aid to support training new staff, such as a video training that could be self-paced.

Study Results: General Conclusions

- Instruments/scope are complex (not difficult) and therefore require more time; increased complexity leads to greater question of whether item is clean
  - Once the system arrives, surgeons generally want to use it right away but the CSSDs may not be prepared, so there is a lot of pressure on them to make arrangements so they can properly support the reprocessing.
  - Materials may specify steps/items not aligned with EU process / needs.
  - Many of the CSSDs commented on the length of time it takes to reprocess complex instruments, especially those sites that have to perform the process manually.
- IFUs viewed as guidance/recommendations
  - Everything moving towards electronic copy – some sites already stating everything must be digital – not necessarily a regulation but more a ease-of-process / storage
  - Sites need to maintain QMS with their own SOPs (Quality Documents); Since the SOPs trump user manuals, the manuals are not widely used by reprocessing staff (unless SOPs are not yet in place). Instead, they are usually filed away or attached to the SOP as an appendix.
  - As people's experience level increases, type of and use of supporting materials changes.



Case Study – Validating Reprocessing IFUs

Study Overview

The purpose of the study was to:

- Ensure intended users can perform the steps described within the Reprocessing Instructions in the expected use environment in a safe and effective manner.
- Assess the overall usability of the reprocessing instructions.
- Identify and record any unanticipated / unexpected use-errors.

The study was conducted:

- In the summer of 2015.
- In simulated CSSD environments in two cities in the U.S.
- To fulfil summative activities expected by FDA.

Study Overview

Methodology

- Standard summative style usability study
- No training was provided as part of this study.
- Mix of participant types
- Forced to rely on the manual to complete tasks
- Research team recorded use errors and probed on root cause of those errors.

Study Results: General

- Participants commented that they do not normally use the IFU while reprocessing instruments in the CSSD.
- Many participants refer to wall charts, but they are more common in the decontamination area.
- There were a significant number of observed use errors even as participants referred to the IFU while reprocessing. Many of the issues were due to:
  - Content
  - Terminology
  - Layout
  - Organization

Study Results: Use Errors

Common use errors included:

- Failing to inspect with the required level of magnification.
- Missing or eliminating steps.
- Failing to use the indicated cleaner (ex: water instead of disinfectant).
- Failing to use the indicated supplies (ex: brush).
- Not performing a step for long enough, or performing a step for too long.
- Not priming or flushing all indicated areas of an instrument or priming/flushing incorrect areas.
- Misinterpreting flush direction.
- Spraying or flushing with water below the recommended psi.
- Not disassembling products that required disassembly prior to reprocessing (failing to remove disposable pieces).
- Failing to actuate and rotate parts while cleaning.

3 Why Does Reprocessing Matter?

GASTROENTEROLOGY
Pseudomonas Infection of the Biliary System Results From use of a Contaminated Endoscope

"…Although the instrument had been cleaned repeatedly with an automatic endoscope cleaning machine, P. aeruginosa survived on residual moisture left in the channels of the endoscope…"

1987

CDC MMWR WEEKLY
Bronchoscopy-Related Infections and Pseudoinfections – New York

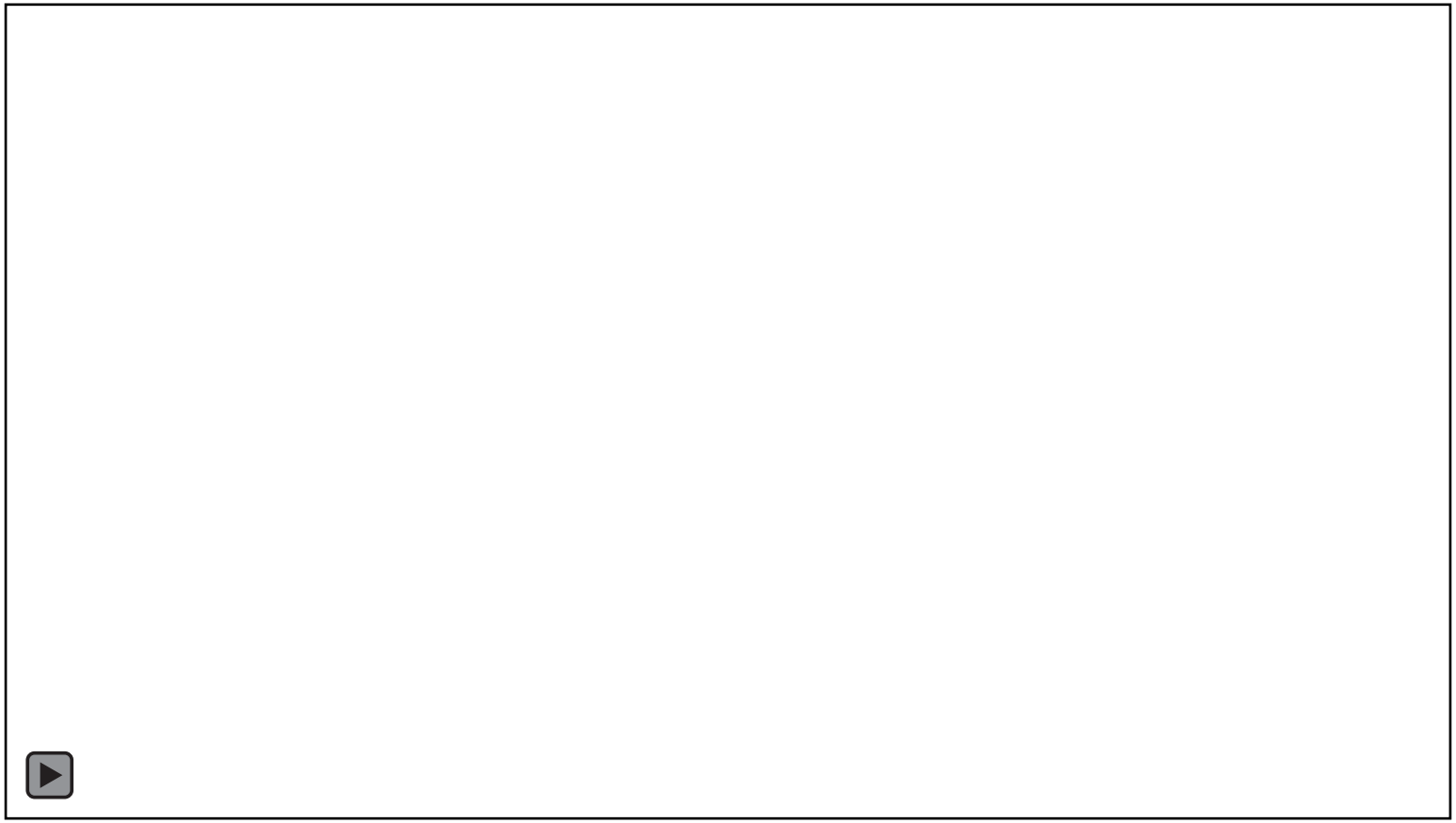
"The New York State Department of Health received reports of three clusters of culture-positive bronchoscopy specimens … Between patient uses, bronchoscopes had been cleaned, visually inspected, leak tested, and processed.."

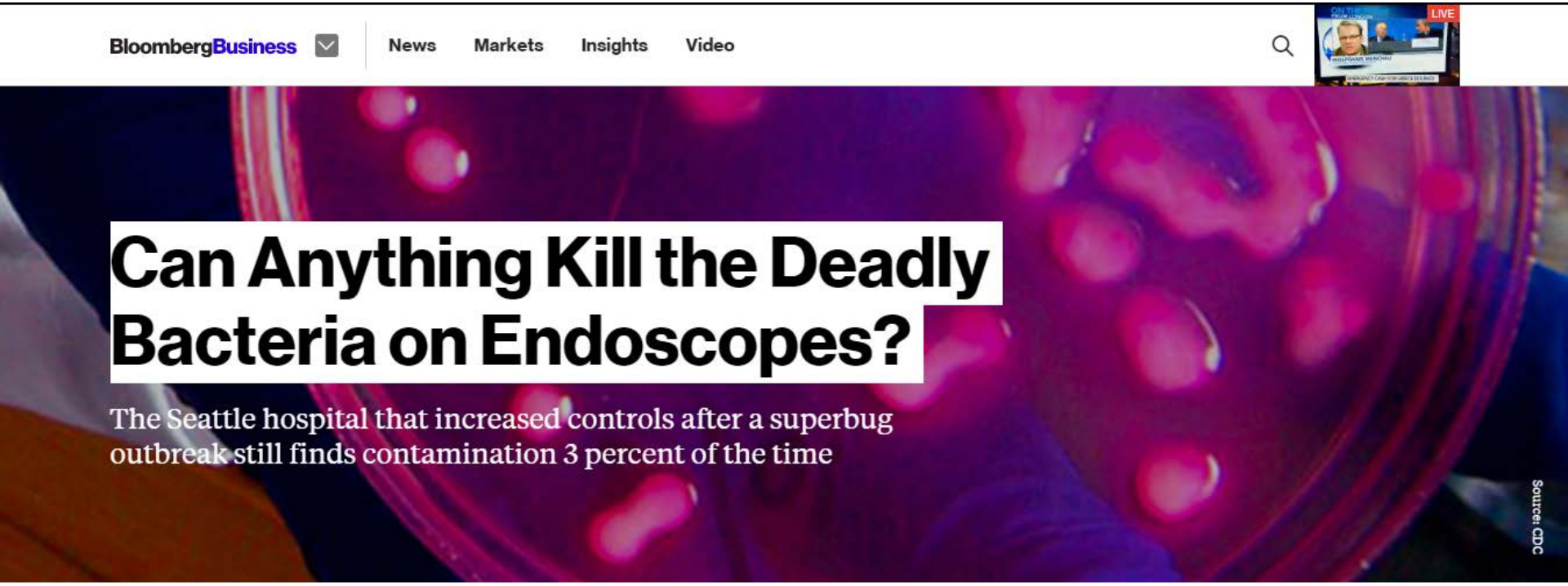
1998

WASHINGTON POST
Widening superbug outbreak raises questions for FDA, manufacturers

"Young is among seven patients at UCLA who were infected with a hard to treat "superbug" that hospital officials traced to two specialized scopes that they said were contaminated despite being thoroughly cleaned."

2015





"Hospitals are discovering that it's nearly impossible to clean endoscopes… ***Even with more diligent cleaning, the hospital found that 3 percent of the scopes tested positive for contamination and had to be re-cleaned***."

http://www.bloomberg.com/news/articles/2015-04-01/bacteria-lingers-on-medical-scopes-even-with-heightened-cleaning

Another outbreak from tainted scopes suspected at an L.A.-area hospital

Huntington Memorial Hospital in Pasadena has notified patients who may have been infected by a contaminated medical scope made by Olympus Corp. Above, Olympus showcases its ERCP scopes at a Washington medical conference in May. (Chad Terhune/Los Angeles Times)

"The widening problem is sure to ratchet up pressure on the Food and Drug Administration and scope makers to better address concerns about patient safety. Both regulators and the companies have been under fire for ignoring earlier warnings on the infection risk."

http://www.latimes.com/business/la-fi-hospital-scope-infections-20150819-story.html

#4: Inadequate Reprocessing of Endoscopes and Surgical Instruments

Factors that can contribute to the improper cleaning of instruments include:

- The intricacy of the instruments (e.g., devices with narrow channels or movable parts to disassemble).
- Lengthy or incomplete manufacturer instructions for cleaning.
- Time pressures placed on reprocessing staff.
- Insufficiently trained personnel.

Source: Health Devices 2014 November. ©2014 ECRI Institute □www.ecri.org/2015hazards

New lawsuits filed against scope maker in deadly UCLA superbug outbreak

Dr. Zachary Rubin, medical director of clinical epidemiology at UCLA's Ronald Reagan Medical Center, left, and Dr. Robert Cherry, chief medical and quality officer for UCLA Health System, take questions last month (April) about a superbug outbreak. (Damian Dovarganes/Associated Press)

"In addition to wrongful death, the complaint accuses Olympus of negligence and fraud in selling and promoting a defective scope "so as to maximize sales and profits at the expense of the health and safety of the public."

http://www.latimes.com/business/la-fi-ucla-superbug-patients-20150317-story.html

The global reprocessed device market is expected to post 19.3% CAGR

The market is approximated to expand to US$2.58 billion in 2020, from US$0.78 billion in 2013

The greatest motivator is the **massive cost savings** for the medical intuitions.

- The average hospital could save between US$0.5M – US$2M per year by reprocessing devices rather than opting for single use devices or buying new ones.*

*From a report by The Association of Medical Device Reprocessors (AMDR)

Source: Transparency Market Research June 22, 2015 http://www.transparencymarketresearch.com/article/reprocessed-medical-devices.htm

4 Existing Guidance

Existing Guidelines – FDA Guidance

FDA Guidance – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (issued: March 17, 2015)

- *"Manufacturers of reusable devices should consider device designs that facilitate easy and effective cleaning, as well as any necessary disinfection or sterilization by the users."*
- Six Criteria for Reprocessing Instructions
- Appendix E: Instrument Complexity:
  - *"The FDA has identified a subset of medical devices that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed."*

FDA Safety Communication – Supplemental Measures to Enhance Duodenoscope Reprocessing (issued: August 4, 2015)

- *"The FDA is aware of instances of persistent bacterial contamination even following strict adherence to manufacturers reprocessing instructions."*

Existing Guidelines – FDA Guidance

Table 1 **510(k) Submissions Should Include Reprocessing Validation Data for** **Laparoscopic Instruments and Accessories with Any of the Following Design Features**
Lumens (with internal surfaces that are not smooth, have internal ridges or sharp angles, or are too small to permit a brush to pass through)
Hinges
Interior device channels
Sleeves surrounding rods, blades, activators, inserters, etc.
Adjacent device surfaces between which debris can be forced or caught during use
O-rings
Devices with these or other design features that cannot be disassembled for reprocessing
Stopcocks

Existing Guidelines – AAMI TIRs

AAMI TIR 12: 2010 – Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

- *"Manufacturers of reusable medical devices have the responsibility to support product label claims of reusability by providing complete and comprehensive written instructions for the handling, cleaning, disinfection, testing, packaging, sterilization, and, if applicable, aeration of their products."*

AAMI TIR 30: 2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

- *"If cleaning protocols that could be used for verification were in wide use today, they could help ensure that (…) a device can be reliably disinfected and/or sterilized before it is used on the next patient."*

AAMI TIR 55: 2014 – Human factors engineering for processing medical devices

- *"Medical device processing is performed by and is dependent on humans, and therefore human factors engineering needs to be considered in the design of the various elements of processing."*

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Summary of the Existing Guidelines

Good Design and Good Instructions!

1. **Be aware of your design:** Make devices as uncomplicated as reasonably possible.
2. **Be aware of your reprocessors:** Make your instructions clear, especially for the users that will be reprocessing your device.
    - Potentially low paid technicians or volunteers with minimum certification required*, in a high pressure, time-constrained environment.
    - Nurses and surgical support staff with potentially minimal training on how to start reprocessing at the point-of-use.
3. **Be aware of the complex interaction between your users and your design:** Make sure that your instructions are comprehensive enough that your instrument can be consistently and thoroughly cleaned and disinfected, even with the complicated channels, lumens, hinges, etc.

*Currently, not all states require sterile reprocessing technicians to be certified.

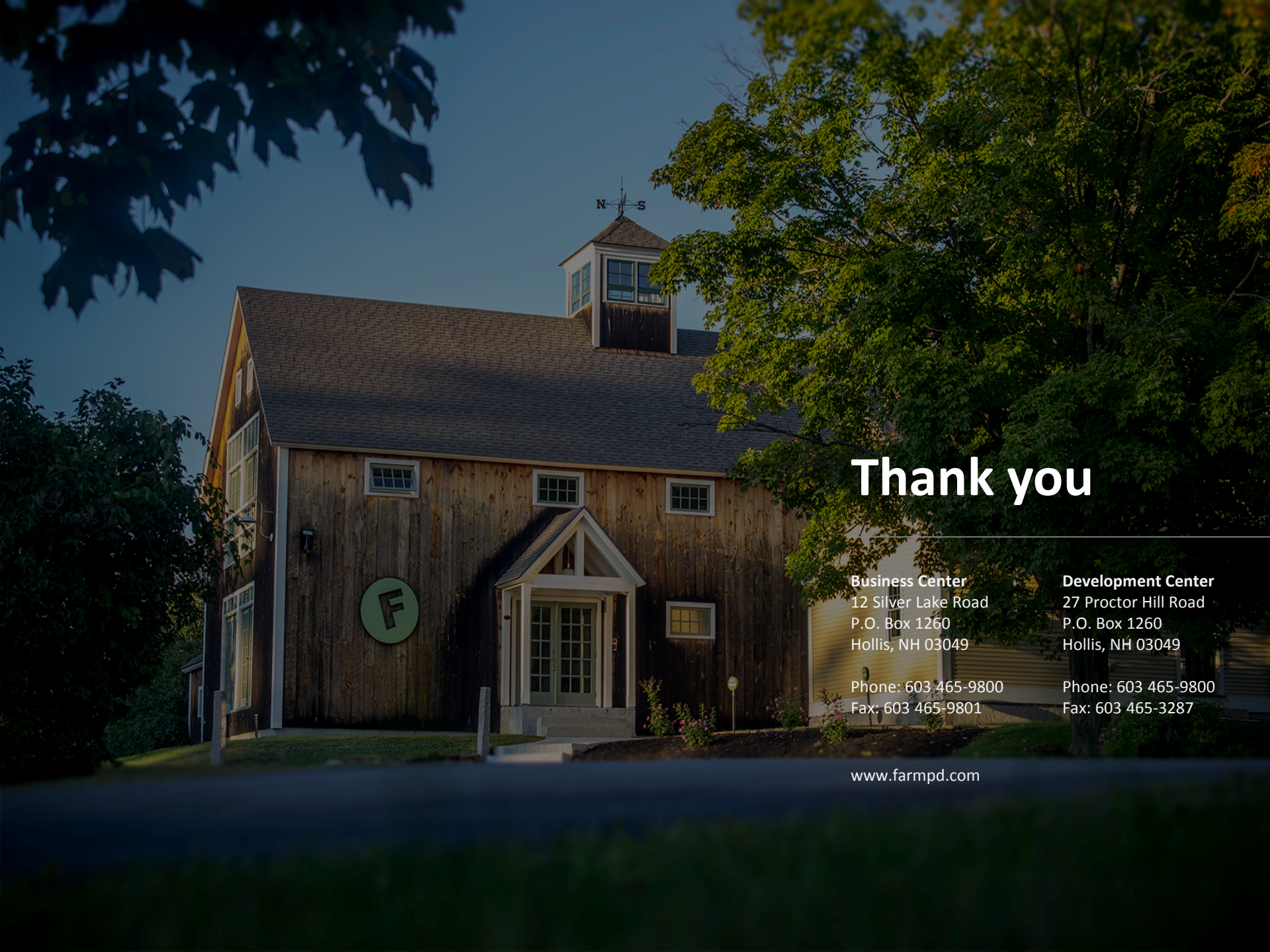
Conclusions

Conclusions: Takeaways for the Industry

The market is growing!

- With improvements to reprocessing procedures, the perception around reprocessed devices will improve – encouraging continued growth in the industry.
- With increased public perception of reprocessing challenges (UCLA, etc) OEMs and regulatory agencies are under greater scrutiny to design devices that can be sterilized effectively.

- **Follow the guidance (FDA, AAMI TIRs)**
  - Consider reprocessing and cleaning in the device/instrument's risk analysis.
  - Consider ALL end users – reprocessors and OR support staff will also be using your instrument, and are responsible for ensuring that it can be effectively and safely reused.
- **Consider reprocessing constraints when making design decisions**
- **Consider the usability of your IFU**



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