Behavioral Course Objectives

1. Discuss the FDA position on the use and replacement of the Steris System 1® Processor.
2. Discuss what factors FDA states you should consider in selecting an alternative product to the Steris System 1® Processor.
3. Discuss the Association of periOperative Registered Nurses (AORNs) suggestions for planning for alternatives to the Steris System 1® Processor.
4. Discuss the ECRI Institutes information provided in assisting your transition to an alternative product to the Steris System 1® Processor.

FDA

- Provided a Questions and Answers About the Steris System 1® Processor (SSI)
- Hosted a call December 7, 2009 for healthcare facilities using SS1
- Hosted a stakeholder call on December 10, 2009
  - Proposed a 3 to 6 month timeline for transition
Determine which specific reprocessing methods are appropriate for each device based on "written recommendations and instructions for use from the manufacturer of the device to be reprocessed".

Determine what reprocessing methods and equipment are available in your facility, or can be acquired.
STERIS System 1E™ (SS1E) Liquid Chemical Sterilant Processing System

- FDA Cleared April 5, 2010
- "The SS1E can be used to process reusable heat-sensitive devices such as endoscopes and their accessories that cannot be processed using thermal methods.
- "Because the rinse water is not sterile, devices processed using liquid chemical sterilization cannot be assured to be sterile.

Ref: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/RecentlyApprovedDevices/ucm207499.htm

Users should be aware of the following, if they choose to use the SS1E:

- "SS1E should be used only for processing heat-sensitive semi-critical and critical devices that are compatible with the S40 sterilant and the processing system and cannot be sterilized by other legally marketed traditional sterilization methods validated for that type of device.

Ref: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/RecentlyApprovedDevices/ucm207489.htm

Users should be aware of the following, if they choose to use the SS1E:

- Devices that are not validated for processing in the SS1E should not be processed in the SS1E.
- Following processing, the devices should be used immediately.
- The S40 sterilant used in the SS1E has not been validated for use with the SS1 and should not be used in the SS1.

Ref: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/RecentlyApprovedDevices/ucm207489.htm

Planning for alternatives to the STERIS System 1 safety, financial impact and work flow are just some of the issues health care professionals are considering as they develop transition plans to alternative methods for reprocessing endoscopic instrumentation in light of the FDA notice regarding concerns with the STERIS System 1.

Ref: http://www.aorn.org/News/Managers/February2010Issues/STERIS

Other methods may damage equipment
- "Each alternative has distinct issues to consider, including financial implications, staff education and safety, for both patients and health professionals."
- If choose a manual soak with a HLD (which has probably been phased out), staff training including proper ventilation and PPE will be important

Ref: http://www.aorn.org/News/Managers/February2010Issues/STERIS
Financial impact
- Potential purchase of equipment, instruments and supplies
- Structural or environmental modifications for installation of new equipment or ventilation requirements
- Staff training so everyone is practicing these alternatives safely
- Estimates are a million dollars for a 200-bed facility
- Estimate for a ASC with 2 ORs is $60,000 to $100,000

Collaborate with a team of stakeholders to determine the safest and most cost effective approach
- Especially for endoscopy, general surgery and surgical specialties (orthopedic, gynecology and urology)
- Find the safest alternative that fits the budget and personnel work flow

ECRI Institute

1. A nonprofit organization dedicated to bringing the discipline of applied science research to discover which medical procedures, devices, drugs, and processes are best, all to enable you to improve patient care."
2. Information on STERIS System 1 can be obtained at https://www.ecri.org/Forms/Pages/STERIS-System-1-(SS1)-Replacement.aspx

ECRI Institute

Documents available at the website
2. ECRI Institute STERIS-SYSTEM 1 Sterile Processing Systems and Accessories: FDA Extends Transition Period to 18 Months (February 4, 2010)(S0192 03)
3. ECRI Institute SPECIAL REPORT S0192 02: STERIS-System 1 Sterile Processing Systems and Accessories: ECRI Institute Provides Guidance for Developing a Transition Plan
4. Reprocessing Alternatives for Flexible Endoscopes
5. 2010 Top 10 Technology Hazards

ECRI Institute

- FDA could take a stronger regulatory action in the future if potential risks remain unaddressed
- This could impact availability of parts, no new trays or connectors, consumables (including sterilant), and service
  - Could affect a facility's ability to meet reprocessing demand for some period of time
- Because of high level of attention even in lay media
  - Could put your facility at legal risk even if the SS1 is not the actual source of the injury or infection
- Don’t rush decision
  - Careful, comprehensive, and analytical process
Transition team (IC, GI, CS, clinical engineering and affected departments)
May require multiple sterilization or disinfection systems
Do not suggest transition to manual processing of flexible endoscopes
“...this can introduce serious inconsistencies in the process as well as increase exposure of staff to potentially harmful chemicals and vapors.”

Identify how many SS1 systems are used in which clinical departments
Each department should submit a list of medical devices (identify device type, manufacturer, and model) currently processing
Departments should list whether crucial services will be impacted if an alternative reprocessing method is not available (help prioritize)
Based on medical device manufacturers’ instructions identify compatible reprocessing methods or agents

Identify compatible reprocessing options currently available in your facility and how much of the SS1 reprocessing stream can be handled by these available options
Do you add more of the current options?
Do these options meet turnaround time needed, if not how much additional inventory would be needed?
How will workflow be affected?
Are additional steps needed like wrapping?
What accessories and consumables are needed?

If needs cannot be met, determine for new equipment
What infrastructural requirements are needed
Or do you replace current medical devices with devices that offer more desirable reprocessing options (practical and economical)
Ensure adequate training
Ensure access to necessary accessories, connectors, and documentation
“If your facility identifies critical devices for which no reprocessing alternatives or replacement devices appear to be available, notify FDA to express your concerns

Options
EO scope compatibility but long processing time
Gas-plasma sterilizers have lumen length and diameter scope limitations
AERs are acceptable for devices outside the OR

2010 Top 10 Technology Hazards
A result of investigating and consulting on device-related incidents
Information found on medical device problem reporting databases of ECRI Institute and other organizations
List based on
Likelihood and severity of reports
Recalls and other actions
Examination of published literature
Arbitrary list and may not be your top 10
ECRI Institute
No. 1 Technology Hazard
Cross-Contamination from Flexible Endoscopes
- Incidents of pathogen transmission with large numbers of patients notified
- Almost always a result of
  - Failure to follow established cleaning and disinfection/sterilization guidelines
  - Use of damaged or malfunctioning equipment

Ref: 5

ECRI Institute
No. 1 Technology Hazard
To avoid this technology hazard
- Must tailor process to individual endoscope
- Must properly prepare the accessories also
  - Irrigation, insufflation, suctioning tools
  - Cleaning brushes
    - "They should either be single-use, disposable items or, if reusable, be decontaminated at least daily. The device manufacturer should provide information regarding brush size for cleaning devices with lumens." (AAMI ST79 section 7.5.3.2)

Ref: 5

ECRI Institute
No. 1 Technology Hazard Avoidance
To avoid this technology hazard, continued
- Ensure model specific reprocessing protocols for each flexible endoscope
- Periodically review protocols to ensure clear, comprehensive and reflect current environment
- Ensure all steps from precleaning at treatment site to safe and aseptic transport are addressed and documented

Ref: 5

ECRI Institute
No. 1 Technology Hazard Avoidance
To avoid this technology hazard, continued
- If using an AER, ensure
  - Endoscope is compatible with AER and disinfecting/sterilizing agent
  - Appropriate channel adapters are available and staff familiar with these
  - Staff knows maintenance schedules and performs them
- Ensure documented protocols are available to staff who are trained to understand and follow them

Ref: 5

Safety Communication from FDA, CDC, and the VA on “Preventing Cross-Contamination in Endoscope Processing” (Nov/09)
- Cleaning and disinfection/sterilization are two separate steps
- Endoscopes and accessories that contact sterile tissue must be sterilized before each use
- Liquid Chemical Sterilization
  - “Sterilization with a liquid chemical sterilant may not convey the same sterility assurance as sterilization achieved using thermal or low temperature chemical gas/plasma/vapor sterilization methods. Liquid chemical sterilants should be limited to reprocessing only critical devices that are heat-sensitive and incompatible with other sterilization methods.”

Ref: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm

Considerations for the Replacement of Your Steris System 1® Processor
Access the Resources Discussed Today
Start Planning Now
Discussion of Your Process for the Replacement of Your Steris System 1® Processor

- Team and members?
- System wide or individual facility decision?
- How accessed what needed to be transitioned, and processes (sterilization/HLD) needed?
- Process of obtaining up-to-date instructions from the medical device manufacturers?
- How accessed the number of replacement units needed?
- How accessed additional costs (wraps, monitors, ventilation, plumbing, electrical, water treatment)?
- Did you move toward terminal sterilization as the standard of care for all scopes?
- Budget-special funds?

Presenter Biography

Martha Young, BS, MS, CSPDT
President of Martha L Young, LLC
SAVYY Sterilization Solutions

Martha Young has over twenty eight years of experience in the area of sterilization and disinfection. Ms. Young lectures around the world and has numerous publications on infection prevention with an emphasis on improving the performance of the sterilization process. She recently retired after 31 years with 3M and has a consulting company for healthcare manufacturers and providers.

She is a member of IAHCSMM, AORN (Professional/Practice Issues Chair for AORN specialty assembly for Sterile Processing Materials Management) and APIC and a certified Central Sterile Processing and Distribution Technician. She is a member of several AAMI working group committees that are developing recommended practices and the Special Technical Editor for the 3M sponsored in-service in healthVIE.com (formerly Managing Infection Control) and writes a quarterly column for OR Manager.

Ms. Young was named in 2007 by HPN as one of the 30 Pros to Know who are the most influential in Healthcare Sterile Processing.