



October 28, 2002

Dear Member:

Currently the Food and Drug Administration (FDA) does not actively regulate hospitals that engage in the practice of resterilizing "opened-but-unused" single-use medical devices. However, as part of their ongoing effort to ensure that patient care is rendered in a safe and effective manner, the FDA is requesting comments on:

- Whether or not hospitals have written policies or procedures for handling sterile, single-use medical devices that are opened, for whatever reason, but are unused;
- How hospitals determine if a single-use medical device that has been opened but unused is contaminated; and
- What types of single use devices are resterilized because they are opened-but-unused.

The FDA will use the comments they receive to determine whether they regulate hospital resterilization of "opened-but-unused" single use medical devices.

In response to the FDA's request for comments, the American Hospital Association (AHA), the Association of Professionals in Infection Control and the American Society for Healthcare Central Services Professionals are jointly conducting this **confidential** survey of hospital procedures related to sterile single-use medical devices that have been opened, but not used in a patient procedure.

We need your participation in this important survey. The data we collect will help us frame our comments on the FDA's request and will help determine whether or not hospitals' resterilization practices will be regulated in the future. To get the best and most complete responses, we suggest that in responding to the survey, the following areas of your facility should be consulted for information: infection control, central sterile processing, risk management and perioperative nursing. Survey results will be analyzed and shared with the FDA in aggregate form only, without hospital specific identifiers.

Thank you very much for your assistance. **Please fax your completed survey by Friday, November 8, 2002 to (888) 820-5681.** Remember to only return one completed survey per facility. If you have any questions about the survey, please contact AHA's Roslyne Schulman at rschulman@aha.org.

Sincerely,

American Hospital Association
American Society for Healthcare Central Services Professionals
Association of Professionals in Infection Control

Special Hospital Survey: Practices Associated with "Opened-But-Unused" Single Use Devices

(This is a confidential survey. No information that could identify individual hospitals will be released to the FDA.)

GENERAL HOSPITAL DEMOGRAPHICS

1. How many staffed beds does your hospital have?
 Less than 24 25-49 50-99
 100-199 200-299 300-399
 400-499 More than 500
2. Please identify the type of hospital.
 Non-government, not-for profit Investor-owned, for-profit
 Government, non-Federal Government, Federal
3. Is your hospital a teaching facility? No Yes
4. How many operating rooms (ORs) does your hospital have? _____ ORs
5. How many surgical procedures are done in the OR annually (i.e. your estimate for the past 12 months)?
Inpatient procedures _____
Outpatient procedures _____
6. Is your hospital located in a: rural area suburban area urban area?

INFORMATION ABOUT HOSPITAL PRACTICES AND PROCEDURES

7. How does your hospital handle sterile single-use medical devices that have been opened but have not been used ("opened-but-unused") in a patient procedure? (Please check all that apply)
 Some or all devices are discarded
 Some or all devices are sent back to the manufacturer
 Some or all devices are separated for subsequent resterilization/reprocessing
 Other (please explain) _____

Please only answer the following questions if your hospital uses ANY resterilized/reprocessed single use medical devices that have been opened-but-unused.

8. Does your hospital have a written policy or written procedure for handling sterile, single-use medical devices that have been opened but have not been used in a patient procedure?
 No
 Yes (If possible, please attach a copy of this policy and return with your survey. Be sure to black out any information that could identify your facility.)
- 8A. If yes to question 8, please check each area that is addressed in your hospital's policy or procedure:
 Cleaning/Decontamination Re-packaging
 Functionality testing Sterilization
 Number of times device can be resterilized Other (please describe)
 Re-labeling _____

Thank you! Please fax your completed survey to 1-888-820-5681.

9. What factors does your hospital consider when deciding WHICH “opened-but-unused” single use medical devices can be safely resterilized/reprocessed (e.g. component material, lumened/non-lumened)?

10. Check all entities/persons that have authority in this decision-making process for handling single use devices that are “opened-but-unused.” (Please check all that apply)

- | | |
|--|--|
| <input type="checkbox"/> Infection Control Committee | <input type="checkbox"/> Central Service/Sterile Processing manager |
| <input type="checkbox"/> Hospital Administration | <input type="checkbox"/> Medical and/or surgical staff |
| <input type="checkbox"/> OR manager and/or staff | <input type="checkbox"/> Safety/Risk Management manager |
| <input type="checkbox"/> Department specific manager | <input type="checkbox"/> No defined level of authority exists for decision process |
| <input type="checkbox"/> Other, please explain _____ | |

11. Where does resterilization/reprocessing of “opened-but-unused” single use medical devices take place? (Please check all that apply)

- some or all devices resterilized/reprocessed within my hospital
- some or all devices resterilized/reprocessed through a third-party reprocessing company
- some or all devices returned to original manufacturer for reprocessing/recycling

Please only answer the following questions if resterilizing/reprocessing of ANY “opened-but-unused” single use medical devices takes place WITHIN THE HOSPITAL:

12. For how long has your hospital been resterilizing/reprocessing “opened-but-unused” single use medical devices within your hospital? _____ years

13. Under which of the following circumstances would your hospital resterilize/reprocess “opened-but-unused” single use medical devices: (Please check all that apply)

- devices that are removed from their sterile packaging outside of a sterile field
- devices that are removed from their sterile packaging within a sterile field and there is no visible contamination with blood or other bodily fluids
- devices that are removed from their sterile packaging within a sterile field and there is visible contamination with blood or other bodily fluids
- devices have been dropped or otherwise contaminated but not used in a patient procedure

14. Does your hospital’s protocol include criteria to determine whether a single use medical device that has been “opened-but-unused” is contaminated? No Yes

- 14A. If yes to question 14, what criteria is used to determine if a single use medical device that has been “opened-but-unused” is contaminated? (Please check all that apply)

- Visible contamination with debris indicates contamination
- Visible contamination with blood and/or body fluids indicates contamination
- Hand contact with unwrapped device indicates contamination
- Any device that is removed from its sterile packaging within sterile field indicates contamination
- Dropped device indicates contamination
- Individual healthcare workers decision
- Other (please explain) _____

Thank you! Please fax your completed survey to 1-888-820-5681.

15. Resterilizing/reprocessing that is done in your hospital is done by: (Please check all that apply)
- Individual clinical department (i.e., Interventional Radiology, Cardiac Catheterization Lab, GI Endoscopy) and they are responsible for conducting *all* steps of process
 - OR and OR staff is responsible for conducting *all* steps in process
 - Central Service/Sterile Processing department is responsible for conducting *all* steps in process
 - Cleaning and packaging done in individual department with sterilization being done in Central Service/Sterile Processing department
 - Cleaning and packaging done in individual department with sterilization being done in OR area.
 - Other (please explain) _____

16. Has your facility had any adverse patient outcomes associated with the use of “opened-but-unused” single use devices that have been resterilized within your facility?
- No Yes

16A. If yes to question 16, please describe:

17. In the last 12 months, approximately how many dollars do you estimate that your hospital has saved by resterilizing/reprocessing “opened-but-unused” single-use medical devices within your facility? \$_____ per year

18. What types of “opened-but-unused” single-use medical devices do you resterilize within your hospital? (Please check all that apply)

- | | |
|---|--|
| <input type="checkbox"/> custom surgical packs | <input type="checkbox"/> cardiac catheters |
| <input type="checkbox"/> drapers | <input type="checkbox"/> lumen catheters |
| <input type="checkbox"/> gowns | <input type="checkbox"/> non-lumen catheters |
| <input type="checkbox"/> grafts | <input type="checkbox"/> endoscopy equipment |
| <input type="checkbox"/> sutures | <input type="checkbox"/> GI biopsy forceps |
| <input type="checkbox"/> breathing circuits | <input type="checkbox"/> other (please list) |
| <input type="checkbox"/> biopsy forceps | <input type="checkbox"/> orthopedic devices |
| <input type="checkbox"/> other devices, please list below or attach a list: | <input type="checkbox"/> burrs |
| _____ | <input type="checkbox"/> bits |
| _____ | <input type="checkbox"/> implants |
| _____ | <input type="checkbox"/> ortho shavers |
| | <input type="checkbox"/> pins |
| | <input type="checkbox"/> sizers |
| | <input type="checkbox"/> other (please list) _____ |

19. If we have questions about your responses, may we contact you? No Yes

Contact name: _____

Organization: _____

Phone number: _____

Thank you very much for your assistance. **Please fax your completed survey by November 8, 2002 to 1-888-820-5681.**

Thank you! Please fax your completed survey to 1-888-820-5681.