



November 26, 2002

The Honorable Mark McClellan, MD, PhD  
Commissioner of Food and Drugs  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: [Docket No. 02N-0456] Determining Hospital Procedures for Opened-But-Unused, Single-Use Medical Devices; Requests for Comments and Information (67 *Federal Register* 55269), August 28, 2002.

Dear Dr. McClellan:

The American Hospital Association (AHA), the Association of Professionals in Infection Control and Epidemiology, the American Society for Healthcare Central Service Professionals (ASHCSP), and the Federation of American Hospitals (FAH) are pleased to provide the Food and Drug Administration (FDA) with comments on its request for information on determining hospital procedures for opened-but-unused (OBU) single-use medical devices. To help in preparing our comments, we worked together to survey our memberships using a jointly-designed instrument called the "Special Hospital Survey: Practices Associated with 'Opened-But-Unused' Single-Use Devices." **Based on our research and knowledge, we do not believe there is a need for further FDA regulation in this area.**

It is common in hospitals that a sterile single-use device (SUD) is opened in preparation for a medical procedure but, for a variety of reasons, is not subsequently used. Typically, these "opened-but-unused" devices are cleaned/decontaminated, resterilized and repackaged either at the hospital or through a third-party reprocessor. Some original equipment manufacturers provide written instructions on how to conduct these activities. If this is the case, third-party reprocessors and hospitals will follow these instructions. However, if there are no instructions provided by the original equipment manufacturers, then it is appropriate for the reprocessor/hospital to develop their own written policies and protocols for each step of the process based on standard principles. Another typical scenario occurs in the context of assembling custom surgical packs. Sterile processing professionals assemble, wrap and sterilize these packs, which may consist of many devices labeled for single-use.

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We are pleased that the FDA has historically recognized that this practice does not provide a public safety concern and has excluded it from regulation. **It is essential that health care facilities be permitted to continue to conduct these activities without being subjected to burdensome, costly, and unnecessary regulation.** We are aware of no scientific evidence that would establish a public health risk associated with the cleaning, resterilization and repackaging of OBU SUDs. Since they have not, by definition, been previously used on a patient, the use of these devices should pose no risk of patient-to-patient infection, provided that the standard processes of cleaning/decontaminating, resterilizing and repackaging are properly conducted. There is strong evidence that the bioburden or contamination levels of micro-organisms on reusable medical devices/instruments is relatively low (orders of 1-2 logs).<sup>1,2</sup> Items in which the original seal has been opened, but are unused, are several tiers removed from the potential for contamination as compared to reusable devices. We believe this already offers a substantial margin of safety.

Proper cleaning/decontamination practices, sterilization and resterilization processes have been routinely performed for many years on a wide variety of medical devices – both reusable and single use. Our organizations believe hospitals can uphold the essential goal of safety, without resorting to regulatory requirements that might unnecessarily strain the resources of health care providers.

Finally, we continue to believe that FDA does not have jurisdiction under the Federal Food, Drug, and Cosmetic Act to regulate hospital procedures for handling sterile single-use devices that have never been used in a patient, even if the device package was opened. While the agency has the authority to regulate the manufacture of medical devices, it does not have the authority to regulate the practice of medicine.

However, because there is not a great deal of information available on these practices, our organizations worked together to develop a survey to examine current hospital practices. A representative group of 675 hospitals responded to our survey. While detailed results of our survey are contained in Appendix A, some of the key findings are:

- **Only 25 percent of hospitals used resterilized OBU SUDs.**
- **Most hospitals either have their own written policies/procedures for handling OBU SUDs or rely on the policies of third-party reprocessors.**
- **Of hospitals that use resterilized OBU SUDs, most (56 percent) rely on third-party reprocessors; only 16 percent indicate that they resterilize OBU SUDs within the hospital.**

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<sup>1</sup> Chu NS, Chan-Myers H, Ghazanfari N, Antonoplos P. Levels of naturally occurring micro-organisms on surgical instruments after clinical use and after washing. *Am J Infect Control* 1999 Aug;27(4):315-9.

<sup>2</sup> Rutala WA, Gergen MF, Jones JF, Weber DJ. Levels of microbial contamination on surgical instruments. *Am J Infect Control* 1998 Apr;26(2):143-5.

- **No hospitals responding to the survey indicated that they have had any adverse patient outcomes associated with the use of hospital-resterilized OBU SUDs.**

In general, our survey data indicate that very few hospitals would resterilize devices opened within a sterile field and in which there was visible contamination. A majority of hospitals are willing to resterilize only devices that were opened outside a sterile field or opened within a sterile field but without visible contamination. However, it must be clarified that, as a matter of practice, proper cleaning, decontamination, and repackaging of potentially contaminated devices precede sterilization and include standard quality control processes, such as biological indicators and other sterilization cycle monitors.

Most importantly, we are impressed with the lack of *any* reported adverse events associated with the resterilization of OBU SUDs. However, we are not surprised given the low percentages of hospitals resterilizing these devices as a whole, combined with what we know of the low relative risk of contamination in these instances, as noted above. This risk appears negligible in contrast to the real risks of adverse events associated with medical devices related to use, and supports the observations by many, including the FDA, that OBU SUDs contribute little-to-nothing to endemic complications of health care and do not warrant further regulation and associated expenditures.

Further, based on responses from this survey, the ASHCSP will be undertaking another initiative to develop a model policy for distribution to its member organizations. This model policy will be based, in part, upon the written policies received from survey respondents. We are hopeful that this step will further assure the safety of resterilizing OBU SUDs.

However, we continue to believe that of greater concern is the lack of standards for original equipment manufacturers that would make the "single use" label meaningful, evidence-based and standardized. Although original equipment manufacturers have a financial incentive to label devices "single use," we understand that the FDA believes that it does not have the statutory authority to require original equipment manufacturers to justify this labeling. We hope that the FDA would support legislation that would give the agency the statutory authority to provide for "truth in labeling" for devices that original equipment manufacturers describe as "single use." In addition, as noted above, some original equipment manufacturers do provide instructions for resterilizing their SUDs. Hospitals are appreciative of this sort of guidance when it is available and we would urge the FDA to encourage other original equipment manufacturers to provide resterilization instructions for SUDs.

In summary, we believe our letter and supporting information provide compelling evidence that patient safety and care are in no way compromised by the practice of reuse/resterilizing of "open-but-unused" single-use devices in our nation's hospitals. We hope the FDA will also determine that there is no need for further regulation in this area.

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Thank you for the opportunity to comment on this important issue. We look forward to working with the FDA in the future and we are available to discuss in more detail the results of our survey upon request. Please direct any questions regarding this letter to Roslyne Schulman, AHA's senior associate director for policy development, at (202) 626-2273.

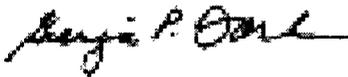
Sincerely,



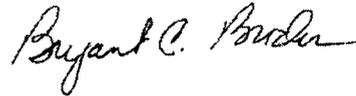
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## Appendix A: Survey Results

In response to the FDA's request for comments, our organizations collaborated on issuing a survey. The AHA sent out 6,323 surveys, ASHCSP sent out 636 surveys and APIC sent out a notice to its members indicating that the survey was available on-line and 823 individuals downloaded the survey form. Over a two-week period, we received a total of 675 completed surveys, which were subsequently entered into a database and analyzed. A series of data tables are attached herein that provide the results of this survey. A copy of the survey instrument is also attached. One important note: Some of the responses to survey questions sum to more than 100 percent. This is because on a number of the questions we posed, respondents could check more than one answer, if applicable to their facility.

### Representativeness of Sample

The respondents generally appear to be representative of the universe of hospitals in terms of staffed-bed size and urban/suburban/rural location. In tables 1 and 2 below, our survey responses are compared to the AHA's Annual Survey responses for identical or similar questions.

Table 1: STAFFED BEDS

Number of Staffed Beds	OBUSUD Survey	AHA Annual Survey
<24	50 (7%)	339 (6%)
25-49	105 (16%)	1,027 (18%)
50-99	124 (18%)	1,342 (23%)
100-199	156 (23%)	1,439 (25%)
200-299	105 (16%)	743 (13%)
300-399	47 (7%)	391 (7%)
400-499	31 (5%)	212 (4%)
>500	52 (8%)	317 (5%)
No entry	5 (1%)	N/A

Table 2: LOCATION

	OBUSUD Survey	AHA Annual Survey
Rural	308 (46%)	2175 (44%)
Suburban	168 (25%)	N/A *
Urban	175 (26%)	2740 (56%)
No entry	24 (4%)	N/A

\* Note: The AHA Annual Survey defines facilities located in metropolitan areas as "urban" and those in non-metropolitan locations to be "rural". Suburban areas would generally be defined as "urban" using this definition.

### How Hospitals Handle OBU SUDs

Question 7 in the survey asks, "How does your hospital handle sterile single-use devices that have been opened but have not been used ('opened-but-unused') in a patient procedure?" The responses are as follows:

- 512 (76%) of hospitals indicated that they discard some or all devices
- 106 (16%) of hospitals send some or all devices back to manufacturer
- 168 (25%) of hospitals separate some or all devices for reesterilization
- 103 (15%) of hospitals checked “other”
- 9 (1%) hospitals did not respond to this question

The larger the hospital (as measured by staffed-bed size), the more likely they were to use reesterilized OBU SUDs or to return the devices to the manufacturer. Federal hospitals are less likely to reesterilize than other hospitals. The percent of hospitals that reesterilize does not appear to be related to teaching status or to urban/rural location, although suburban hospitals are somewhat more likely to reesterilize devices than urban or rural facilities.

### **Responses For Hospitals That Use Any Resterilized OBU SUD**

Questions 8 and above were intended only for those hospitals that use any reesterilized OBU SUD. However, as will be discussed below, many respondents did not follow these instructions.

#### Written policy/procedure for handling OBU SUDs

Question 8 asked, “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?” The responses are as follows:

- 175 (52%) of hospitals answered “yes”
- 152 (45%) of hospitals answered “no”
- 10 (3%) hospitals did not answer this question

Question 8A applied to hospitals that have written policies/procedures. It asked which areas are addressed in a hospital’s policy or procedure and offered six possible areas to choose from plus an “other” response. Respondents (N= 175) indicated that the areas addressed in these policies include:

- cleaning/decontamination (N=60, 34%)
- repackaging (N=49, 28%)
- relabeling (N=36, 21%)
- sterilization (N=68, 39%)
- functionality testing (N=37, 21%)
- number of times device may be reesterilized (N=34, 19%)
- other areas (N=80, 46%)

Slightly more than half of hospitals (52%) have written policies or procedures for how they handle sterile SUDs that have been OBU. The larger the hospital, the more likely the hospital is to have a written policy – with 67% of large hospitals (400 or more beds) having written policies compared to 40% of small hospitals (less than 100 beds). Neither

teaching status nor urban/suburban/rural location seems to influence whether hospitals have written policies/procedures.

As a caveat, it is important to note that many hospital respondents did not follow the written directions in the survey requesting that only hospitals that use any resterilized OBU SUDs should answer questions 8 and forward. Therefore, a significant part of the reason that so many hospitals indicated that they did not have a written policy is because they *do not resterilize OBU SUDs* and instead they simply discard the devices. *Other hospitals indicated in the "other" choice in question 8A that their hospital would not have its own written policy because they defer such decisions to third party reproprocessors' policies/procedures (N=44, 25%).*

#### Factors Hospitals Consider To Decide Which OBU SUDs Can Be Safely Resterilized

Question 9 asked, "What factors does your hospital consider when deciding WHICH "opened-but-unused" single-use medical devices can be safely resterilized/reprocessed? This was written as an open-ended question because the collaborating organizations had a difficult time identifying, in advance, which factors could influence such a decision. Although the responses have not been quantified in the same manner as in other questions in this survey, the factors identified most often by respondents, in no particular order, include:

- List of devices stipulated by third-party reprocessing company
- Follow manufacturer statements or instructions
- Consider component material
- Only non-lumened devices
- Follow FDA guidelines or FDA listed items
- Consider the potential risk for contamination
- Consider the potential risk for functional failure of device
- Consider the potential cost savings
- Consider the ease of cleaning and/or sterilization
- Consider the degree of invasiveness of device

#### Persons Or Entities With Authority In How OBU SUDS Are Handled

Question 10 asked respondents to "Check all entities/persons that have authority in this decision-making process for handling single use devices that are 'opened-but-unused.'" The results indicate that hospitals bring into this important decision-making a wide variety of persons/entities. However, of all respondents to this question (N=337), the majority indicated that the following have such authority:

- Operating room (OR) manager and/or staff (N=231, 69%)
- Infection control committee (N=218, 65%)
- Central service/sterile processing manager (N=167, 50%)

Other persons/entities, such as the hospital administration, a department specific manager, medical/surgical staff, safety/risk manager are also involved in decision making in many hospitals. Very few hospitals (N=8, 2%) indicate that there is no defined level of

authority in their decision-making process. Larger hospitals tend to have more individuals involved in the decision making process than small hospitals.

#### Location Where Resterilization Of OBU SUDs Occurs

Question 11 asked respondents “Where does resterilization/reprocessing of ‘opened-but-unused’ single use medical devices take place?” The respondents (N=337) indicated:

- 56% (N=190) said some or all of these devices are resterilized through a third-party reprocessing company
- 16% (N=53) said some or all of these devices are resterilized/reprocessed *within the hospital*
- 15% (N=51) said some or all of these devices are returned to the manufacturer for reprocessing/recycling

Large hospitals (more than 400 beds) were more likely than small hospitals (less than 100 beds) to use a third-party reprocessor or to return devices to the original manufacturer for resterilization. Small and large hospitals were equally likely to perform resterilization in-house (N=27 and 9 respectively, 20%). Also, rural hospitals were more likely (N=30, 20%) to do in-house resterilization than urban (N=8, 10%) or suburban (N=12, 13%) hospitals. Conversely, suburban and urban hospitals were more likely (65% and 64% respectively) to use a third-party reprocessor for resterilization of OBU SUDs than rural hospitals (N=67, 44%).

#### **Responses For Hospitals That Resterilize OBU SUDs On The Hospital Premises (“In-House”)**

Questions 12-18 were intended to apply *only* to hospitals that resterilize OBU SUDs in-house. A caveat to the following summary/analysis is that although only 53 (16%) hospitals indicated that they performed in-house reprocessing, *more than double this number continued to answer questions 12-18.*

#### Period of Time That Hospital Has Been Resterilizing OBU SUDs In-House

Question 12 asked, “For how long has your hospital been resterilizing/reprocessing “opened-but-unused” single use medical devices within your hospital?” The mean number of years that hospitals have been resterilizing devices in-house is seven years. Most hospitals (N=62, 58%) that perform in-house resterilization have been doing this for 10 years or less.

#### Circumstances Under Which Hospital Would Resterilize OBU SUD

Question 13 asked, “Under which of the following circumstances would your hospital resterilize/reprocess ‘opened-but-unused’ single-use medical devices?” Respondents (N=108) indicated they would be willing to resterilize/reprocess:

- Devices opened outside a sterile field (N=60, 56%)
- Devices opened within a sterile field and no visible contamination (N=64, 59%)

- Devices dropped or otherwise contaminated but not used in a procedure (N=44, 41%)
- Devices opened within a sterile field and there is visible contamination (N=9, 8%)

While a majority of hospitals are willing to resterilize devices that were opened outside a sterile field or opened within a sterile field but without visible contamination, very few hospitals would resterilize devices in which there was visible contamination. Fewer than half of respondents indicate they would be willing to resterilize unused devices that were dropped or otherwise contaminated.

#### Determining Whether an OBU SUD Has Been Contaminated

Question 14 asked, “Does your hospital’s protocol include criteria to determine whether a single-use medical device that has been ‘opened-but-unused’ is contaminated?” For those with such criteria, question 14A asked which criteria are used to indicate contamination. 38% of respondents (N=41) indicated that their protocol did include such criteria. The criteria these respondents used to determine contamination included:

- Visible contamination with blood an/or body fluids (N=30, 73%)
- Visible contamination with debris (N=26, 63%)
- Device dropped (N=20, 49%)
- Hand contact with unwrapped device (N=19, 46%)
- Device removed from its sterile packaging within a sterile field (N=19, 46%)
- Individual health care workers decision (N=11, 27%)
- Other (N=4, 10%)

#### Location Within Hospital Where Resterilization Is Performed

Question 15 asked respondents to indicate which department within their hospital is responsible for resterilizing/reprocessing OBU SUDs. Because it is known that in some hospitals, the steps for cleaning, resterilizing and repackaging devices may occur in different locations, such options were laid out in the survey. Responses (N=108) to this question are as follows:

- Central Service/Sterile Processing department conducts all steps (N=54, 50%)
- OR and/or OR staff conducts all steps (N=24, 22%)
- Cleaning/packaging done in individual department with sterilization done in Central Service/Sterile Processing department (N=11, 10%)
- Cleaning/packaging done in individual department with sterilization done in OR area (N=3, 3%)
- Other (N=15, 14%)

Large hospitals are much more likely (N=10, 91%) than small hospitals (N=24, 49%) to perform all steps in sterilization within the central service/sterile processing department. This is likely due to the fact that smaller hospitals may not have a distinct central service/sterile processing department and these functions are performed elsewhere within the facility.

### Adverse Patient Outcomes

Question 16 asked, “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?” Of those responding (N=94), none indicated any such adverse events.

### Types of OBU SUDs Resterilized Within Hospital

Question 18 asked, “What types of ‘opened-but-unused’ single-use medical devices do you resterilize within your hospital?” The survey included a list of devices commonly known to be resterilized. Respondents (N=108) could also add other devices to the list. The devices noted to be resterilized by hospitals include:

- Bits (N=32, 30%)
- Burrs (N=29, 27%)
- Biopsy forceps (N=25, 23%)
- GI biopsy forceps (N=22, 20%)
- Pins (N=15, 14%)
- Ortho shavers (N=14, 13%)
- Gowns (N=14, 13%)
- Drapers (N=14, 13%)
- Sutures (N=13, 12%)
- Custom surgical packs (N=12, 11%)
- Grafts (N=12, 11%)
- Orthopedic devices (N=10, 9%)
- Sizers (N=9, 8%)
- Other Orthopedic devices (N=9, 8%)
- Implants (N=8, 7%)
- Non-lumen cardiac catheters (N=3, 3%)
- Endoscopy equipment (N=3, 3%)
- Lumen cardiac catheters (N=1, 1%)
- Other endoscopy equipment (N=1, 1%)

Appendix B

**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)?

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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.**