DECONTAMINATED SINGLE-USE DEVICES: AN OXYMORON THAT MAY BE PLACING PATIENTS AT RISK FOR CROSS-CONTAMINATION

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ABSTRACT

OBJECTIVE: To determine whether reprocessed single-use devices would meet regulatory standards for sterility and meet the same materials standards as a new device.

DESIGN: The study included single-use and reusable biopsy forceps and papillotomes and a reusable stone retrieval basket. The suitability of these devices for cleaning and disinfection or sterilization was examined.

METHODS: Testing of cleanability was conducted on devices contaminated with technetium 99-radiolabeled human blood. Instruments were cleaned using hospital recommended practices for manual cleaning. Gamma counts per second were determined before and after cleaning to localize contaminants, which were additionally visualized using light and scanning electron microscopy. X-ray photoelectron spectroscopy was used to quantify contamination elements on the materials tested. Residual bioburden testing on instruments contaminated with microorganisms suspended in coagulable sheep blood was carried out to establish the efficacy of disinfection and sterilization.

RESULTS: All devices remained contaminated after cleaning, but single-use devices and the stone basket tended to be more heavily contaminated than reusable forceps and papillotomes. Cleaning procedures facilitated distribution of contaminants further into the lumens of the disposable forceps. Decreased concentrations of silicon and increased concentrations of carbon and nitrogen suggested that layers of silicon lubricant had been removed and contaminants were organic material. Reusable devices were effectively disinfected, but single-use devices were not. Sterilization could not eliminate the challenge microorganisms completely.

CONCLUSIONS: None of the reprocessed single-use instruments were effectively cleaned, disinfected, or sterilized. This condition may provide an opportunity for the viability of nonresistant or nosocomial organisms and viruses. Additionally, reprocessing procedures may result in material destruction of fragile devices. Cost-saving initiatives that have inspired reprocessing of single-use devices, despite the absence of data establishing the efficacy of decontamination and the durability of materials throughout reprocessing, should be pushed into the background (*Infect Control Hosp Epidemiol* 2001;22:542-549).

Recycling of single-use devices poses two kinds of problems: medical risks that may result in physical and physiological harm and nonmedical problems related to ethics, economic factors, and possible liability. While the reuse of disposables is done for the best possible motives, there is now an argument that patients potentially are being put at risk and hospitals are exposing themselves to the possibility of expensive litigation.[1-6]

A recent report of hepatitis C transmission from patient to patient during endoscopic biopsy procedures[7] has prompted healthcare institutions to pursue the development and use of disposable instruments. At the same time, efforts to reduce the costs inherent in labor-intensive reprocessing are contributing to this interest.

Despite efforts to institute the use of disposable devices to save reprocessing costs, these devices increasingly are being reprocessed. They tend to be more delicate and physically complex than reusable devices,[8] and, unfortunately, data do not exist to establish the efficacy of decontamination and the durability of materials throughout reprocessing.

We designed this study to determine whether reprocessed single-use, small, complex devices will meet standards for sterility[9] and meet the same materials standards as a new device. We compared our results with those found for similar reusable devices. We tested single-use and reusable devices that enter the body via an endoscope and, except for the stone retrieval basket,

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TABLE 1
DEVICE DESCRIPTIONS

	Length (mm)	Inner Diameter (mm)	Luer Lock	Inner Lumen	Inside Material	Outside Material
Single-use						
Biopsy forceps	2,400	2.2	No	1	2 stainless steel wires in high-density polyethylene	Handle: polymer-covered metal coil with high-density polyethylene
Papillotome	2,000	2.0	2	3	Cutting wire	Polyethylene tube
Reusable						
Biopsy forceps	2,300	2.2	No	1	2 polyfile stainless steel wires	Metal coil
Papillotome	1,820	1.8	1	1	Cutting wire	Polyethylene tube
Stone retrieval basket	2,100	2.4	1	1	Polyfile stainless steel wire with basket	Polytetrafluorethylene (Teflon) tube

penetrate the mucosa. The standard for cleaning, disinfecting, and validation of sterilization methods (steam and ethylene oxide [EtO]) of the selected medical devices was defined by the Association for the Advancement of Medical Instrumentation (AAMI) and was designed to be representative of those found in healthcare facilities.[10-12] In this context, contamination refers to the presence of microorganisms and other undesirable material (inorganic and organic soil or biological material) on or in an object. Accordingly, decontamination refers to a process including cleaning and disinfection of a contaminated object. The Spaulding Classification Scheme[13] was used to define the need for a sterility assurance level of 10^{-6}.[14] We hypothesized that the differences in design and materials between disposable and reusable instruments (Table 1) would be reflected in the results of reprocessing.

We used the radionuclide method (RNM), light microscopy, scanning electron microscopy (SEM), and x-ray photoelectron spectroscopy (XPS) as well as microbiological methods to assess the effects of reprocessing.

METHODS

Evaluation of Cleaning and Material Alterations

The RNM is a nondestructive test procedure that uses gamma radiation to visualize contamination on the inner and outer surfaces of the instrument. The exact distribution of the contamination can be assessed before and after cleaning.[15] XPS provides quantitative data about the elemental composition of the surface in question and of the oxidation (chemical binding) state of the identified elements. This method was used to evaluate whether a medical device was reusable from the perspective of materials analysis. Selected elements for this study were those expected to be indicative of organic materials and surface components of the devices. SEM is used for investigating the topography of surfaces and the microstructure of bulk material. Contaminated surfaces are easily visualized as layers or particles, and material damage can be identified.[16]

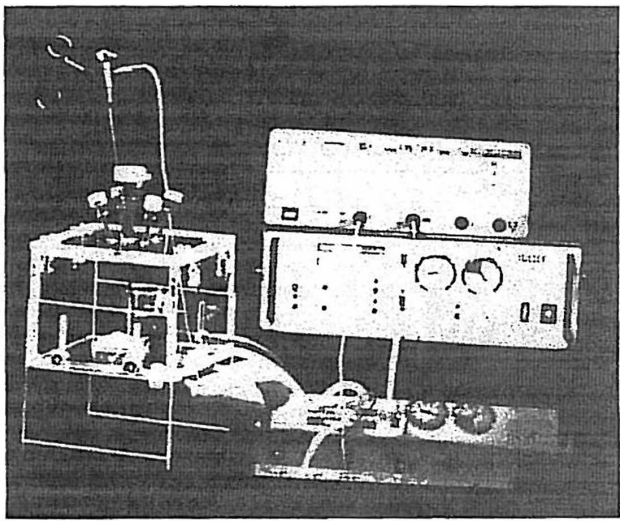

FIGURE 1. Test box.

Test Soil

Native human blood was radiolabeled by adding a mixture of 500 mBq of technetium 99 (Tc-99m) and 5 mL of macroalbumin.

Extracorporeal Simulation

Reproducible test contamination of each device was achieved by simulating the clinical use with an extracorporeal simulation test apparatus consisting of a gas-tight box with ports ("trocars") at the top (Figure 1). The trocars allow the device to be inserted into the box and the device's distal end to be placed into a container holding the test soil (radiolabeled human blood). The box was insufflated with carbon dioxide (CO_2) to an approximate pressure of 15 mm

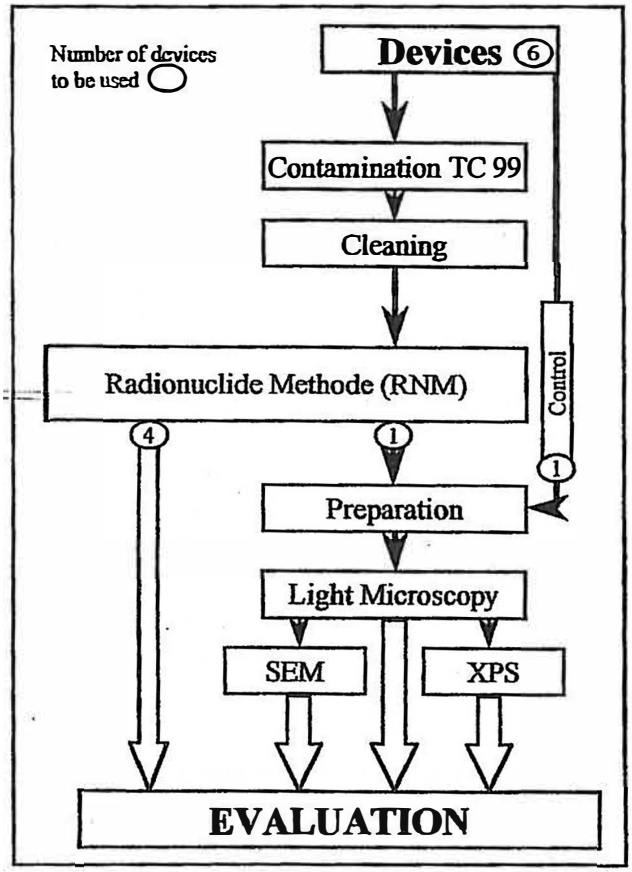

FIGURE 2. Cleaning stage. Abbreviations: RNM, radionuclide method; SEM, scanning electron microscopy; TC, technetium; XPS, x-ray photoelectron spectroscopy.

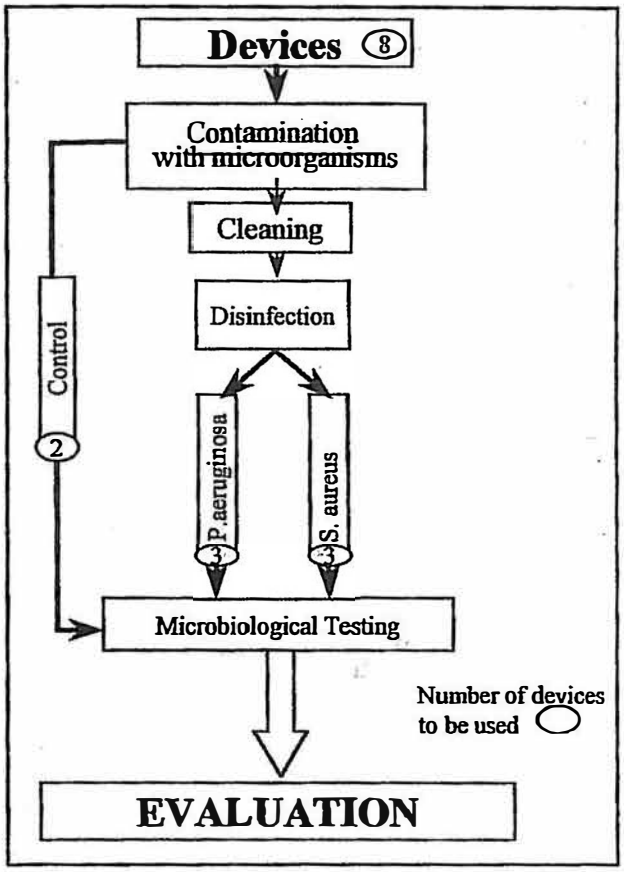

FIGURE 3. Disinfection stage.

Hg, thus simulating the conditions of gastrointestinal endoscopy. During the contamination time of 15 minutes, 20 movements (eg, opening and closing of a forceps) were carried out with each instrument.

Cleaning

Eleven instruments (including a sterile control device) were used for the cleaning test and contaminated by RNM. One of these instruments and the sterile control were reserved for examination by light microscopy, SEM, and XPS (Figure 2). The outside of each contaminated device was wiped visibly clean using a towel, and contamination was measured with a gamma camera to establish baseline levels for localization and quantification of the contamination. The devices then were cleaned under running tap water at 30°C to 35°C for 3 minutes. If possible, the inner lumens were flushed using a 10-mL syringe filled with an enzymatic cleaner (TERG-A-ZYME; Alconox Inc, New York, NY) and the instruments totally submerged in the same cleaning solution for 10 minutes. After completion of the enzymatic soak, the devices were placed in an ultrasonic bath with tap water at 30°C to 35°C for 5 minutes at an output of 40 kHz. Upon completion of the ultrasonic cleaning, the inner lumens were flushed with a syringe, and the external surfaces were cleaned under running tap water at 30°C to 35°C for 3 minutes. Residual water was blown from the lumens with air from a dry syringe, and the outsides were dried with a gauze pad.

Assessment of Cleaning Efficacy

After cleaning, residual contamination on the internal and external surfaces of the instruments again was assessed by measuring the distribution (length of contamination) and intensity of radioactivity by using the gamma camera. Descriptive statistics were used to compare gamma counts per second prior to and after cleaning. The standard for sufficient cleaning was defined as 5 gamma counts per second, based on former investigations.[15] One contaminated device and the control device were examined by light microscopy, SEM, and XPS, as mentioned above, to detect contamination layers and to identify physical alterations of the materials. Quantitative identification of selected elements (carbon, oxygen, nitrogen, silicon, fluorine) was performed by XPS.

Evaluation of Disinfection

Eight instruments were included in this test (Figure 3): six had been contaminated and two remained as sterile controls.

The effectiveness of disinfection was evaluated by inoculation of the devices with *Staphylococcus aureus*

American Type Culture Collection (ATCC) 6538 and *Pseudomonas aeruginosa* ATCC 15442. The concentrations of the test suspensions were adjusted to 10^6 to 10^7 colony-forming units (CFUs)/mL, according to official German guidelines for disinfectant testing.[17]

For soiling of the devices in the test box (as described above), the test organisms were suspended in heparinized sheep blood activated by addition of a heparin antagonist (PROTAMIN 1000; Unipath/Oxoid, Wesel, Germany) to enable coagulation.

Cleaning of the devices was performed as described above. For disinfection, the channels of the devices were filled with 2% alkaline glutaraldehyde solution (CIDEX PLUS; Johnson & Johnson Medical, Arlington, TX) and submerged for 20 minutes at a temperature of 20°C to 25°C. The lumens then were flushed with tap water, using a syringe, and the outside was cleaned under running tap water. Residual water was blown from the lumens with air from a dry syringe, and the outsides were dried with a gauze pad.

Evaluation of Sterilization

Twenty devices were included in this test: 18 were designated for sterilization (9 with EtO, 9 with steam), and 2 devices remained as controls. Each set of 9 devices was divided into three subsets of three and exposed to half of a sterilization cycle (Figure 4). Spore suspensions (0.5-5×10^6/mL) of *Bacillus subtilis* var *niger* (ATCC 9372), for EtO cycles, and *Bacillus stearothermophilus* (ATCC 12980), for steam cycles, as defined by AAMI standards, were used as challenge organisms. The devices were inoculated in the test box with spore suspension only (ie, without additional organic load).

Each device was packed in an appropriate wrap prior to EtO or steam sterilization. Half-cycle sterilization was performed according to the International Standardization Organization's ISO/DIS 14937.[18]

To achieve gas sterilization, we used a half cycle of a validated process in an EtO sterilizer (type 300I0VS; DMB Apparatebau, Mainz, Germany).[19] A leakage test was conducted, followed by a prevacuum down to 200 millibar absolute. Automatic moisturizing of the devices at 90% relative humidity preceded the inflow of the EtO-CO_2 mixture (6% to 94%), building up a pressure of 5.5 bar at 55°C for 30 minutes. Pressure during the aeration phase was approximately 200 millibar absolute, followed by a 15-minute inflow of sterile air and subsequent evacuation to approximately 200 millibar absolute.

Steam sterilization procedures included three evacuations to 130 millibar absolute with steam pulses between them (fractionated prevacuum), followed by sterilization at 134°C with a holding time of 1.5 minutes.

To obtain baseline data on the distribution of contamination within the devices, the instruments were aseptically cut into segments following sterilization; the first segment was 10 cm in length, and the remaining segments were 20 to 30 cm in length. Under aseptic conditions, the segments were rinsed, vortexed, quantitatively cultured by spin plating 1 mL of rinsing fluid, and finally transferred into tryptic soy broth (TSB) for enrichment culture. Segments undergoing EtO sterilization were incubated at 30°C to 35°C for 7 days, whereas steam-sterilized samples were incubated at 55°C for 7 days.

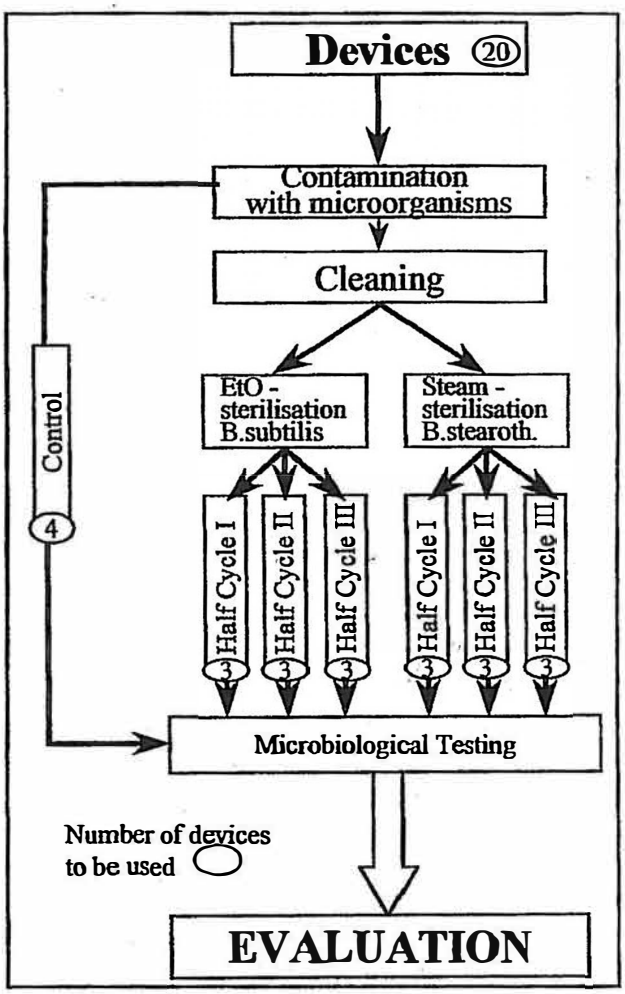

FIGURE 4. Sterilization stage. Abbreviation: ETO, ethylene oxide.

Bioburden Testing

Bioburden assessment was carried out by rinsing of lumened devices and subsequent plating of the rinsing for both contaminated and control devices. Nonrinsable instruments (biopsy forceps) were cut at 10 and 20 cm from the tip (for the Olympus forceps [Olympus Optical Co (Europe), Hamburg, Germany]) or 30 and 60 cm from the tip (for the radial jaw forceps), and the segments placed into two sterile tubes containing 50 mL of TSB. The remaining pieces of the instruments were cut into 10-cm segments and cultured together in TSB. Papillotomes and the stone basket were rinsed with 20 mL of TSB. TSB was collected in a sterile beaker already containing 80 mL of broth, resulting in a total volume of 100 mL. After rinsing, the respective device was cut into 5-cm segments for enrichment culture in the same beaker. As an exception, ULTRATOME XL (Boston Scientific Corporation, Natick, MA), which is provided with two channels, had to be

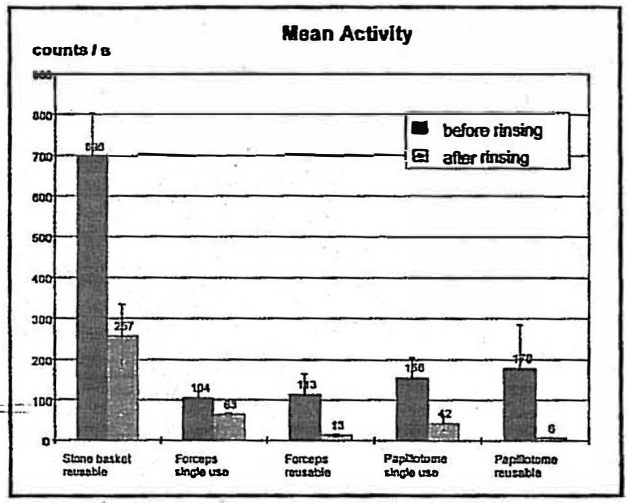

FIGURE 5. Mean quantity of contamination inside the device (in gamma counts/sec).

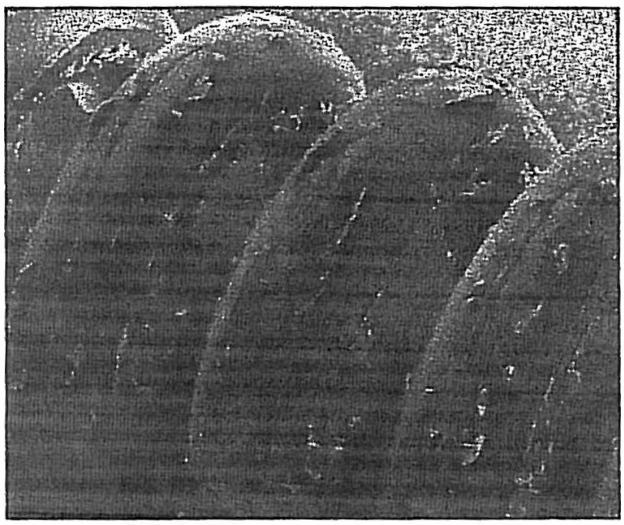

FIGURE 7. Coil of a flexible biopsy device after reprocessing following clinical use.

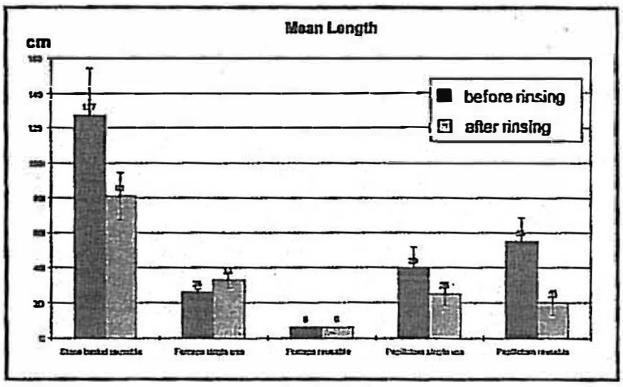

FIGURE 6. Distribution of contamination inside the device (measured from the tip of the device to the end of the contaminated area).

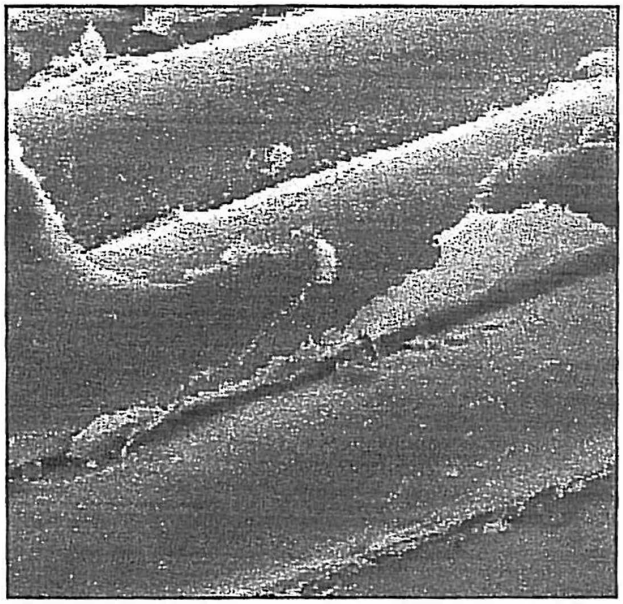

FIGURE 8. Pullwire in a biopsy forceps after reprocessing following clinical use.

rinsed with 2×20 mL of TSB; in this case, beakers with a 60-mL prefill were used (total volume 100 mL).

All tubes were vortexed for 30 seconds, and shaken manually for 30 seconds. The beakers were put on a shaking machine for 15 minutes at 300 minutes^{-1}, followed by plating of 92 µL (using a spiral plater) and 1 mL of broth (using a sterile spatula) on sheep blood agar (Columbia-agar; Heipha, Heidelberg, Germany).

The effectiveness of disinfection was measured in terms of log reduction factors, calculated from the difference in CFUs per device before and after processing. Sterilized devices were assessed for "growth" or "no growth."

RESULTS

Test of Cleaning and Materials

After contamination and cleaning, the gamma camera measurements demonstrated that all devices under investigation remained contaminated, although the level of contamination differed by type of device. Despite undergoing the same reprocessing procedure (Figure 5), the reusable stone basket and the disposable devices tended to retain more test soil, resulting in higher gamma counts than the reusable forceps and papillotomes. The reusable papillotome was the only device that almost achieved the standard for sufficient cleaning (5 gamma counts/sec). For the majority of the instruments studied, as expected, the expansion of the distribution of the test soil within each test device was less after cleaning than before (Figure 6). However, the test soil was further pushed forward into the lumen of the single-use forceps by the cleaning procedure. These results correlated with SEM pictures (Figures 7 and 8) showing the remaining contamination of devices reprocessed after clinical use and localized by RNM.

XPS

A survey spectrum of the surfaces of a new device, as well as of 7 soiled and reprocessed devices, was car-

ried out and evaluated qualitatively. In addition to the identification of elements, a sectional spectrum showing the concentrations of the different elements was determined. For quantification of the elements, a homogeneous distribution had to be assumed. The calculated concentrations of the elements on the surface of the respective samples are listed in Table 2; hydrogen was not taken into account.

Elemental composition analysis of the new device shows carbon, oxygen, and silicon. Due to low information depth of XPS, which is between 2 and 7 nm, no elements of the wire material were detected. Silicon and oxygen are combined as silicone, a lubricant frequently used for medical devices. Carbon is part of hydrocarbons, which completely cover all technical surfaces. No nitrogen could be identified on the surface of the new device. Unlike unused devices, surfaces of soiled and reprocessed instruments show increased concentrations of carbon and nitrogen, explained as traces of residual peptides from blood or other body materials. These residues indicate that cleaning of the devices was not successful.

The decrease in the concentration of silicon either is a covering effect of additional layers of material, reducing the intensity of the covered elements, or is due to a partial removal of the silicone layer during the cleaning process.

TABLE 2
CHANGE IN CONCENTRATION OF ELEMENTS (%) IN BIOPSY FORCEPS (SINGLE-USE), X-RAY PHOTOELECTRON SPECTROSCOPY ANALYSIS*

Device	Carbon	Oxygen	Silicon	Nitrogen
New	14	54	2	< 0.1
Reprocessed	73	17	< 0.1	9

*Measurements were carried out on the surface of the wire, approximately 10 mm below the tip.

TABLE 3
RESULTS OF DISINFECTION: LOG_{10} REDUCTION IN COLONY-FORMING UNITS

	Pseudomonas aeruginosa				*Staphylococcus aureus*			
Device	Control CFU/Device	Replicates			Control CFU/Device	Replicates		
Number	1	1	2	3	1	1	2	3
Single-use								
Biopsy forceps (mean)	6.52	0.00	0.00	0.00		ND*	ND	ND
Papillotome (mean)	7.14	>5.00†	2.96	0.00		ND	ND	ND
Reusable								
Biopsy forceps (mean)	6.05	>5.00†	>5.00†	>5.00†	6.83	>5.00†	>5.00†	>5.00†
Papillotome (mean)	8.36	4.52	>5.00†	>5.00†	7.97	>5.00†	>5.00†	>5.00†
Stone retrieval basket (mean)	7.24	>5.00†	>5.00†	>5.00†	8.81	>5.00†	>5.00†	>5.00†

Abbreviations: CFU, colony-forming unit; ND, not done.
* It was the technical judgment of the laboratory that because *Pseudomonas aeruginosa* is less resistant than *Staphylococcus aureus*, the disinfection stage had already been shown to fail.
† Quantitative culture resulted in >5.0-log_{10} reduction and enrichment broth did not show microbial growth.
‡ Quantitative culture resulted in >5.0-log_{10} reduction and enrichment broth showed microbial growth.

TABLE 4
RESULTS OF STERILITY TESTING

	Steam (*Bacillus stearothermophilus*)		EtO (*Bacillus subtilis*)	
Device	Control Device* (No. Log_{10} of CFUs)	Sterilized Devices	Control Device* (No. Log_{10} of CFUs)	Sterilized Devices
Number	1	9 with growth	1	9 with growth
Single use				
Biopsy forceps†	6.14	7	4.36	4
Papillotome†	6.18	6	5.95	8
Reusable				
Biopsy forceps	4.68	9	4.24	3
Papillotome	6.41	3	5.30	9
Stone retrieval basket	5.95	2	6.34	9

Abbreviations: CFUs, colony-forming units; EtO, ethylene oxide.
* Device was contaminated but not sterilized.
† Devices were physically damaged by the half-cycle steam sterilization process.

Evaluation of Disinfection and Sterilization

Microbial testing after disinfection suggested that reusable devices were effectively disinfected using the procedures described, but disposable devices were not. In both inoculated single-use instruments, the required level of disinfection (>5-log reduction of CFU) was missed (Table 3). Sterilization reduced levels of microbial (spore) contamination for all devices, single-use as well as reusable, but total inactivation of test spores could not be achieved (Table 4). Both single-use devices were physically damaged during sterilization, as evidenced by visible twisting and malformation.

DISCUSSION

Our results suggest that disposable devices are not successfully decontaminated using current standards for reprocessing and may suffer materials destruction during these procedures. Additionally, devices considered reusable might not be effectively decontaminated using well-accepted standards. Although this study did not attempt to find a direct correlation between poorly decontaminated devices and occurrence of disease, our results suggest this possibility. Residual bioburden remaining on insufficiently cleaned devices may hamper disinfection and sterilization procedures and may account for nosocomial infection.[20] The cell walls of either viable or inactivated bacteria in residual material may release lipopolysaccharides with pyrogenic activity,[21] exposure to which could result in unanticipated or as yet unknown immunogenic effects in subsequent patients. Furthermore, microorganisms enclosed in organic or inorganic material (eg, crystals) are protected from sterilizing agents, particularly from EtO.[22] A particular concern is the potential risk for transmission of certain infectious proteins (prions), which demonstrate a higher level of resistance to sterilization than the organisms tested in this study.

As anticipated, differences in the design and materials of single-use devices may have reduced the effectiveness of cleaning, disinfection, and sterilization. The single-use biopsy forceps showed contamination after cleaning that was distributed over a longer distance than it was before cleaning. This distribution indicated that the cleaning agent penetrated inside the device and diluted soluble components of the coagulated blood. However, the design of the device prevented flushing out the dissolved contamination, so it remained for the next use of the instrument with a patient.

The stone retrieval basket was accessible to rinsing, but the contamination could not be washed out totally. The physical design, however, allowed the disinfection agent to penetrate inside the device, destroying most of the microorganisms. Steam was capable of penetrating into the stone basket as well. If the design of a device does not allow access for either the cleaning or disinfection agents, reprocessing very likely will fail.[9,11,20,22] Although the bactericidal spectrum of glutaraldehyde is well documented, inactivation requires physical contact between agent and microorganism. It is very likely that the single-use biopsy forceps could not be decontaminated successfully because the structure of the device prevented efficient contact between cleaner or disinfectant and the inner surfaces of the instrument.

For the reusable forceps, the cleaning and disinfection regimen was adequate to meet the standard for disinfection; however, the sterilization results indicated a definite potential for disease transmission, suggesting that standard hospital sterilization cycles might not sterilize devices due to ineffective cleaning.

Despite these findings, many healthcare institutions believe reprocessed devices, whether designated for single or multiple use, are safe and meet conditions ensuring an equal standard of patient care. However, our results suggest that reprocessed devices do not ensure each patient a clean and sterile device. The decision whether to reprocess these types of accessories has to be based on an accurate and rigorous analysis resulting in validation of device cleaning, including internal cleanliness as well as cleanliness on the outside surfaces.

Using current standards for cleaning, disinfection, and sterilization, none of the reprocessed single-use instruments was suitable for use with subsequent patients. Disinfection and sterilization of disposable instruments could not be performed to required levels, and this condition may provide an opportunity for the viability of potential pathogens, even relatively nonresistant ones. Reprocessing procedures result in materials changes, which add to the degradation and reduced functional integrity of these devices. If cleaning of the reusable devices cannot be performed effectively, the required level of safety cannot be achieved by subsequent disinfection and sterilization. Even if the device is sterile, pyrogenic reactions may result from residual contamination. When reprocessing is performed, routine monitoring of internal cleanliness and sterility should be mandatory in the reprocessing methods. This study may help to identify devices that should not be considered for reprocessing, because their structure does not allow access to all surfaces for cleaning and sterilization.

REFERENCES

1. Green VW. Reuse of disposable medical devices: historical and current aspects. *Infect Control* 1986;7:508-513.
2. Mayhall CG. Types of disposable medical devices reused in hospitals. *Infect Control* 1986;7:491-494.
3. Greene VW. Disinfection and sterilization of disposable devices/equipment. In: Rutala WA, ed. *Chemical Germicides in Healthcare.* Washington, DC: Association for Professionals in Infection Control and Epidemiology; 1995:111-128.
4. Woolard K. Reuse of single-use medical devices: who makes the decision? *Med J Aust* 1996;164:538.
5. Hanlon GW. Reuse of disposables. In: Russell AD, Hugo WB, Ayliffe GAJ, eds. *Disinfection, Preservation and Sterilization.* 3rd ed. Oxford, UK: Blackwell; 1998:777-786.
6. Greene VW. Reuse of disposable devices. In: Mayhall CG, ed. *Hospital Epidemiology and Infection Control.* 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 1999:1201-1208.
7. Bronowicki JP, Venard V, Botte C, Monhoven N, Gastin I, Chone L, et al. Patient-to-patient transmission of hepatitis C virus during colonoscopy. *N Engl J Med* 1997;337:237-240.
8. Buess G, Cuschieri A, Perissat J. *Operative Manual for Endoscopic Surgery.* Vol 1. Berlin, Germany: Springer; 1994.
9. Association for the Advancement of Medical Instrumentation. *Designing, Testing, and Labeling Reusable Medical Devices for*

Reprocessing in Health Care Facilities: A Guide for Device Manufacturers. AAMI TIR no. 12. Arlington, VA: AAMI; 1994.
10. Association for the Advancement of Medical Instrumentation. *Good Hospital Practice: Steam Sterilization and Sterility Assurance.* American National Standards Institute (ANSI)/AAMI ST 45-1993, Arlington, VA: AAMI; 1994.
11. International Standardization Organization. *Sterilization of Healthcare Products: Requirements for Validation and Routine Control: Industrial Moist Heat Sterilization.* Geneva, Switzerland: American National Standards Institute (ANSI)/AAMI/ISO 11134; 1994.
12. International Standardization Organization. *Sterilization of Healthcare Products: Requirements for Validation and Routine Control: Industrial Ethylene Oxide Sterilization of Medical Devices.* Geneva, Switzerland: American National Standards Institute (ANSI)/AAMI/ISO 11135; 1994.
13. Centers for Disease Control and Prevention. Guideline for handwashing and hospital environmental control, 1985. *Am J Infect Control* 1986;14:110-126.
14. European Committee for Standardization (CEN). *Sterilization of Medical Devices: Requirements for Medical Devices to Be Labelled 'Sterile.'* Brussels, Belgium: EN 556, 1995.
15. Schrimm H, Sieber JP, Heeg P, Roth K, Mueller-Schauenburg W, Keller KD, et al. A new method for validating and verifying the cleaning of tubular instruments. *Zentral Sterilisation-Central Service* 1994;2:313-324.
16. Reichl R, Beckmann P, Dreher WF, Inacker O, Mueller E, Heeg P, et al. Innovations in medical technology based on surface and interface analytical methods (part 1). *Zentral Sterilisation-Central Service* 1998;6:222-231.
17. German Society for Hygiene and Microbiology (DGHM). *Guidelines for Testing and Evaluation of Chemical Disinfectants.* Stuttgart, Germany: G. Fischer Publishers; 1981.
18. International Standardization Organization (ISO). *Sterilization of Medical Devices: General Requirements for Characterization of Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process.* ISO/DIS 14937; 1999.
19. European Committee for Standardization (CEN). *Sterilization of Medical Devices: Validation and Routine Control of Ethylene Oxide Sterilization.* Brussels, Belgium: EN 550; 1994.
20. Chaufour X, Deva AK, Vickery K, Zou J, Kumaradeva P, White GH, et al. Evaluation of disinfection and sterilization of reusable angioscopes with the Dutch hepatitis B model. *J Vasc Surg* 1999;30:277-282.
21. Rolansky PF, Dawson ME, Novitsky TJ. Plastics, endotoxins and the Limulus amebocyte lysate test. *J Parenter Sci Technol* 1991;45:83-87.
22. Bond WW. Endoscope reprocessing: problems and solutions. In: Rutala WA, ed. *Disinfection, Sterilization and Antisepsis in Healthcare.* Washington, DC: Association for Professionals in Infection Control and Epidemiology (APIC); 1998:151-163.