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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Specific hygiene issues relating to reprocessing and reuse of single-use devices for laparoscopic surgery

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Abstract
Objective: To determine whether reprocessed single-use devices (SUD) would (1) meet regulatory standards for sterility, and (2) meet the same material standards as new devices or if they pose an infection risk to other patients. *Design:* The study included in the first stage single-use laparoscopic dissection devices and in the second stage a variety of clinically used and reprocessed SUDs. The suitability of these devices for cleaning, disinfection, and sterilization was examined.
Methods: Testing of cleanability was conducted on devices contaminated with radioactively labeled blood. Instruments were cleaned using hospital recommended practices. Gamma counts/second were determined before and after cleaning to localize contaminants, which were additionally visualized using light and scanning electron microscopy (SEM). X-ray photoelectron spectroscopy (XPS) was used to quantify contamination elements on the materials tested. Residual bioburden testing on instruments contaminated with microorganisms suspended in blood prior to reprocessing was carried out to establish the efficacy of disinfection and sterilization.
Results: During the first stage of the study all devices remained contaminated after cleaning, but were effectively disinfected. Sterilization could not eliminate the challenge microorganisms completely. The findings during the second stage — examination of clinically used devices — were as follows: 11% of the sterile packages were damaged; 33% of the devices were incomplete and parts were missing; 54% did not meet the criteria for functionality; light microscopy, SEM, and XPS showed contamination on the outside and inside of all devices. Of the tested SUDs, 40% remained unsterile following resterilization.
Conclusions: None of the reprocessed SUDs were effectively cleaned or sterilized. This may provide an opportunity for survival and growth of non-resistant or nosocomial organisms and viruses. The use of such inadequately reprocessed SUDs increases the risk for the patient, and can lead to nosocomial infection and to legal consequences for the health care facility.

Key words: Reprocessing — Single-use devices — Hygiene problems — Radionuclide method

Recycling of single-use devices poses two kinds of problems: medical risks that may result in physical and physiologic harm, and nonmedical problems that derive from economics, possible liability, and ethics. Whereas the reuse of disposables is done for the "best possible motives," but actually driven by financial reasons, there is now an argument stating that patients are potentially being put at risk and hospitals are exposing themselves to the possibility of expensive litigation [9–11, 13, 17, 22].

Despite efforts to institute the use of disposable devices to save on reprocessing costs, these devices are increasingly being reprocessed. They tend to be more delicate and physically complex than reusable devices, 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 (1) meet standards for sterility [2] and (2) meet the same materials standards as a new device (stage 1) and (3) to examine whether the findings of stage one represents the reality (stage 2). Therefore clinically used and reprocessed devices intended for use in the abdominal cavity, claimed to be sterile and waiting for the next patient, have been collected in different European countries. We compared these results with those found for similar reusable devices. The standard for cleaning, disinfecting, and validation of sterilization methods (ethylene oxide [EtO]) of

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Table 1. Tests performed with each device design

Method / Device Type	RNM	Microbiological tests: *Pseudomonas aeruginosa*	Microbiological tests: *Staphylococcus aureus*	Microbiological tests: *Bacillus subtilis*	Surface analyzing tests: LM	Surface analyzing tests: SEM	Surface analyzing tests: XPS
DCS 12	X	X	X	X	X	X	X
LCS K5	X	X	X	X	X	X	X
LCS 6S		X	X	X			

the medical devices selected was defined by the European Committee for Standardization CEN [7] and was designed to be representative of those found in healthcare facilities [1, 15, 18]. In this context, contamination refers to the presence of microorganisms and other undesirable material (inorganic and organic soil and/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 [5] was used to define the need for a sterility assurance level of 10^{-6} [8].

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

Materials and methods

Stage 1: Laboratory tests

Description of devices involved in the study:

- *Ethicon Endosurgery Endopath DCS 12*, Ch.Nr. M4FF41; 5 mm curved scissors for monopolar cautery, 300 mm working length
- *Ethicon Endosurgery Ultracision Harmonic Scalpel LCS K5*, Ch.Nr. N4HY67, N4HF64 Scalpel, knife down, 15 mm active blade, 5.5 mm diameter, 320 mm working length
- *Ethicon Endosurgery Ultracision Harmonic Scalpel LCS 6S*, Ch.Nr. M4G46T, N4HV53; Ultracision Harmonic Scalpel, 15 mm active blade, 10 mm diameter, 340 mm working length

The matrix, in Table 1 shows which tests have been performed with each device design.

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 and amount of the contamination can be assessed before and after cleaning [21]. X-ray photoelectron spectroscopy (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 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. Scanning electron microscopy (SEM) is used for investigating the topography of surfaces and the microstructure of the bulk material. Contaminated surfaces are easily visualized as layers or particles, and material damage can be identified [18].

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

Extracorporal simulation. Reproducible test contamination of each device was achieved by simulating the clinical use with an extracorporal simulation test apparatus consisting of a gas-tight box with ports ("trocars") at the top (Fig. 1). These trocars allowed to insert the device into the box and to dip the distal end in the container holding the test soil (radiolabelled human blood). The box was insufflated with carbon dioxide (CO_2), usually to a pressure of 15 mm Hg, thus simulating the conditions of laparoscopic surgery. During the contamination time of 15 minutes, 20 movements (e.g., opening and closing of the effectors) were carried out with each instrument.

Cleaning. Five new devices per device design (including a sterile control device) were used for the cleaning test and contaminated by RNM. One of these devices together with the sterile control were reserved for examination by light microscopy, SEM, and XPS. The outside of each contaminated device was wiped visibly clean using a towel, and contamination was measured with a gamma camera (Gaede GMS 586; Im Moos 6, 79112 Freiburg, Germany) to establish baseline levels for localization and quantification of the contamination. One hour after the contamination procedure the devices were inserted into the a special instrument rack for MIS-devices of the washer disinfector Innova SM 700 (BHT Hygienetechnik GmbH, Winterbruckenweg 30, 86316 Friedberg/Derching Germany). Cleaning was performed with the following program and the use of the cleaning agents neodisher FA and N (Chemische Fabrik Dr. Weigert GmbH & Co. KG; Mühlenhagen 85 20539 Hamburg, Germany). The duration of the program is 50 min and includes the following steps:

- 2min pre-wash with cold tap water
- Emptying of the chamber
- 6 min washing at 40°C with neodisher FA 0.5%
- 4 min washing at 60°C with neodisher FA 0.5%
- Emptying of the chamber
- 2 min neutralizing at 32°C with neodisher N, 0.2%
- Emptying of the chamber
- 1 min rinsing with tap water
- Emptying of the chamber

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 contaminated area) and intensity of radioactivity by using the gamma camera. Descriptive statistics were used to compare gamma counts/second prior to and after cleaning. The standard for sufficient cleaning was defined as 5 gamma counts/second, based on former investigations [21]. 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 (Fig.2).

Evaluation of disinfection. Ten devices per design were included in this test (Fig. 3): 6 had been contaminated, 2 remained as sterile controls, 2 as recovery controls.

The effectiveness of disinfection was evaluated by inoculation of the devices with *Staphylococcus aureus* ATCC 6538 and *Pseudomonas aeruginosa* ATCC 15442 (Simicon GmbH, Schumacherring 12, 81737 München, Germany). The concentrations of the test germ suspensions was adjusted to 10^6–10^7 cfu/mL, according to official German guidelines for disinfectant testing [12].

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 (Protaminsulfat available from: Acila GMN, Opelstrasse 14; 64546 Mörfelden-Walldorf; Gemany) to enable coagulation.

Cleaning of the devices was performed as described above followed by

- 10 min thermal disinfection with fully desalinated water at 93°C
- Emptying of the chamber

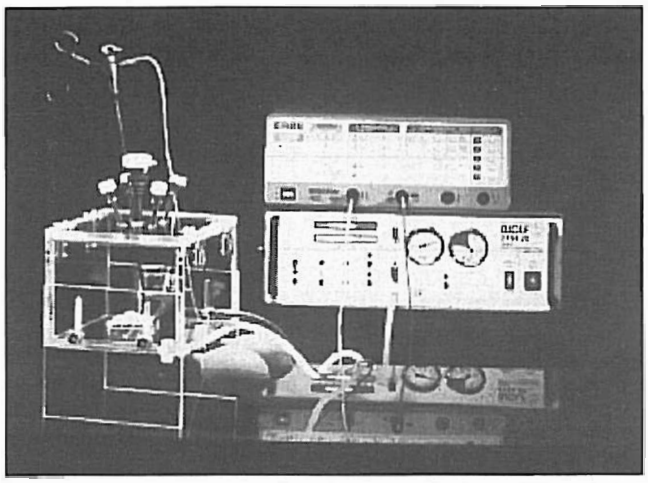

Fig. 1. Test box, to simulate the intraabdominal conditions during laparoscopic surgery. The instruments are inserted via the trocars and the tip is submerged into the test soil. Finally the box is insufflated with 15 mm Hg.

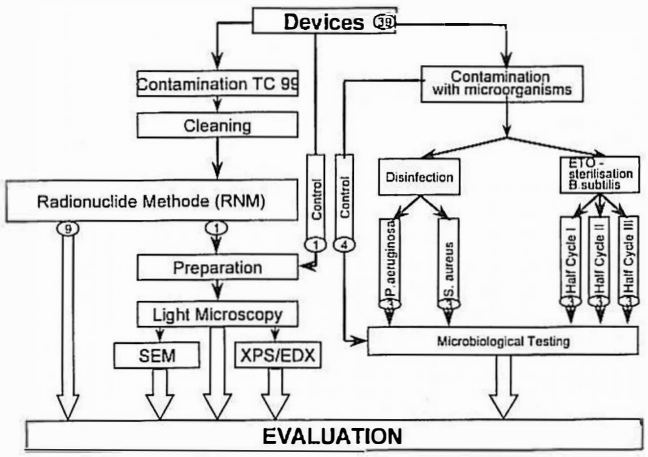

Fig. 2. Follow-up of the test procedures.

- 15 min drying with hot air at 110°C
- 2 min of cooling down

Evaluation of sterlization. Thirty devices were included in this test: 27 were designated for sterilization with EtO, and 2 devices remained as controls. Each set of 9 devices was divided into 3 subsets of 3 and exposed to a half sterilization cycle (Fig. 4). Spore suspensions (0.5 to 5×10^6/ml) of *Bacillus subtilis* var. *niger* ATCC 9372 (Simicon GmbH; Schuhmacherring 12, 81737 München) for EtO cycles, as defined by AAMI standards, were used as challenge organisms. The devices were inoculated in the test box with spore supension only, i.e., without additional organic load.

Each device was packed in an appropriate wrap (Wipak Medical; Steriking 32) prior to EtO sterilization. Half-cycle sterilization was performed according to ISO/DIS 14937 [16].

To achieve gas sterilization, we used a half-cycle of a validated process on a EtO sterilizer (type 30010VS; manufacurer: DMB Apparatebau, Mainz, Germany) [7]. A leakage test was conducted, followed by a prevacum down to 200 mbar absolute. Automatic moisturizing of the devices at 90% relative humidity preceded the inflow of the EtO/CO_2 mixture (6%/94%), building up a pressure of 5.5 bar 55°C for 30 min. Pressure during the aeration phase was approximately 200 mbar absolute, followed by a 15-min inflow of sterile air, and subsequent evacuation to approx. 200 mbar absolute.

In order to obtain baseline data on the distribution of contamination within the devices, the instruments were aseptically cut into segments following sterilization.

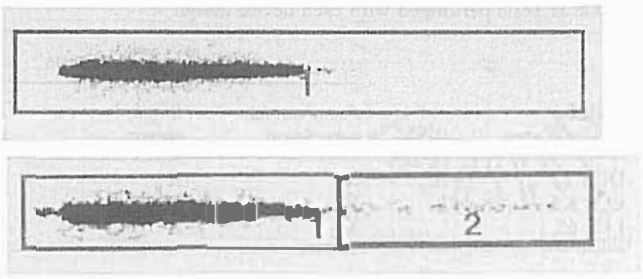

Fig. 3. The distribution of contamination inside LCS B5 before (top) and after (bottom) reprocessing by the use of the radionuclide method. In region 2, which was clean at the beginning, contamination was detected after reprocessing.

Table 2. Change in concentration of elements (%) in biopsy forceps (single-use)

Device	Carbon	Oxygen	Silicon	Nitrogen
New	52	32	5	1
Reprocessed	63	22	2	9

Recovery. The cleaned and disinfected devices including the controls were cut with a bolt cutter in a laminar flow bench. First the cleaned and disinfected instruments were cut followed by the control instruments to avoid cross contamination. After each instrument the bolt cutter was disinfected thoroughly with 70% v/v isopropanol followed by flaming.

The instruments were cut into 3 parts:

- Instruments tip (0–10 cm)
- Central piece (10–20 cm)
- Terminal piece (remaining instrument)

The central and the terminal piece were cut into 2–3 parts. The instruments tip was transferred in Falcon tubes with 45 mL of Tryptic Soy Broth (TSB), the central piece and the terminal piece in Falcon tubes with 40 mL of TSB. The Falcon tubes were shaken mechanically at 500 rpm for 30 min in order to mobilize the test organisms. After shaking 1 mL of the solution was plated onto Tryptic Soy Agar (TSA) and dried under LAF for 10 min. The TSAs were incubated for 48 h at 36 ± 1°C before determing the colony count for the disinfection tests. For sterility testing the incubation time was extended to 7 days when no colony forming units appeared after 2 days.

The effectiveness of disinfection was measured in terms of log reduction factors, calculated from the difference in cfu/device before and after processing (Table 3). Sterilized devices were assessed for "growth" or "no growth" of the test organism (Table 4).

Stage 2: Evaluation of clinically used devices

In total 114 devices had been collected from different hospitals in Germany (96), Italy (4), Austria (4), Switzerland (4), and Great Britain (4). Four devices were reusables. All devices were reprocessed following clinical use. They were claimed to be sterile and were waiting for the next patient. Only some magazines for reloadable staplers had been resterilized, because the package had been opened without using the devices. Because of the variety of device designs collected from the hospitals only a selection of devices, particularly those which were similar to the items tested in stage 1, was included. The following actions were performed:

- All devices were listed and underwent a visual inspection
- The seal strength of 8 pouches was measured
- 14 devices were inspected by light microscopy prior to the test for functionality
- 9 devices were tested for sterility
- 9 devices were investigated by light microscopy, scanning electron microscopy, and photoelectron spectroscopy

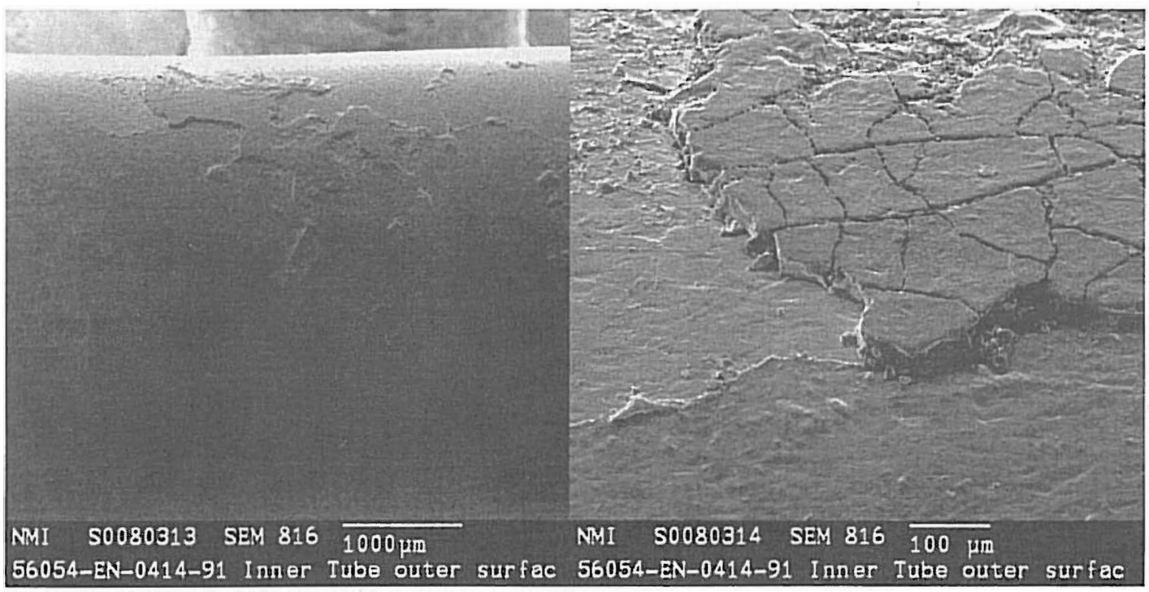

Fig. 4. In two magnifications, the inner surface of the shaft of a harmonic scalpel (LCS K5) 60 mm above the distal end. The instrument had been clinically used and was reprocessed for reuse.

Results

Laboratory test of cleaning and materials

The follow-up of the test methods used during the project is shown in Fig. 2. 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. After cleaning neither in the monopolar scissor (4%) nor in the 5 mm Ultrasonic Harmonic Scalpell (21%) could a remarkable reduction of test soil in terms of reduction of gamma counts be detected. Furthermore, the test soil was further pushed forward into the lumen of the harmonic scalpel during the cleaning procedure (Fig. 3). These results correlated with the SEM pictures (Fig. 4) showing the remaining contamination of reprocessed devices localized by RNM.

X-ray photoelectron spectroscopy (XPS)

A survey spectrum of the surfaces of a new device as well as of two soiled and reprocessed devices was carried 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 dirstribution 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. Because of the low information depth of XPS, which is between 2 and 7 nm, no elements of the metal material were detected. Siliziu and oxygen are combined to form silicone, a lubricant which is frequently used for medical devices. Carbon is part of hydrocarbons which completely cover all technical surfaces exposed to the environment. No nitrogen could be identified on the surface of the new device. Unlike new devices, surfaces of soiled and reprocessed instruments show increased concentrations of carbon and nitrogen, which have to explained as traces of residual peptides from blood or other body substances. These residues indicate that cleaning of the devices was not successful.

The decrease in the concentration of silicon is either a covering effect of additional layers of material reducing the intensity of the covered elements or is due to a partial removal of the silicon layer during the cleaning process (Table 2).

Evaluation of disinfection and sterilization

Microbial testing after disinfection suggested that devices as well as disposable devices were effectively disinfected using the procedures described. In both inoculated single-use instruments, the required level of disinfection (>5 logs reduction of cfu) was reached (Table 3). Sterilization reduced levels of microbial (spore) contamination for all devices, but total inactivation of test spores could not be achieved (Table 4).

Results of Stage 2: Clinically used and reprocessed single use devices

Thirteen (11%) of a total of 114 packages were found to be damaged. Fifteen of 45 (33%) of the received Ultracision devices were incomplete. Eight packaging samples of reprocessed devices (six different types) were examined for seal strength. The investigations of the relative peel resistance yielded values between 0.9 and 5.6 N/cm.

Table 3. Results of disinfection (log_{10}): Reduction in colony-forming units

	Pseudomonas aeruginosa				*Staphylococcus aureus*			
	Control cfu/device	Replicates			Control cfu/device	Replicates		
Device	1	1	2	3	1	1	2	3
DCS 12	6.1×10^6	0	0	0	1.5×10^6	0	0	0
LCS 6S	7.2×10^5	0	0	0	6.8×10^6	0	0	0
LCS K5	5.4×10^5	0	0	0	8.7×10^6	0	0	0

Table 4. Results of sterility testing

	EtO (*B. subtilis*)	
	Control device[a] (No. Log^{10} of cfu)	Sterilized devices (n = 9)
Device	(n = 1)	No. with growth
DCS 12	9×10^6	6
LCS 6S	9×10^5	8
LCS K5	6.7×10^5	4

[a] Device contaminated but not sterilized

Five CS 6S Ultracision Harmonic Scalpells, and three LCSC 6S Ultracision Harmonic Scalpells, and six DCS monopolar scissors were selected for functionality tests. Eight of 14 devices, involved in functional testing, failed. These functional tests included the measurement of the force needed to actuate the device, evaluation of the cutting ability of the scissors, tests of the isolation of monopolar scissors, and, for Ultracision devices, the functionality of the ultrasonic transducer.

Most of the inspected devices showed residual contamination in the hinges, (Figs. 5 and 6) under the isolation coat, on the blades and inside the shaft (Ultracision LCS). Even on plain surfaces (Fig. 7) remaining contamination was detected. Furthermore, four of nine devices tested proved to be unsterile. Nine Ultracision devices were inspected using SEM and XPS. Contamination and damage of nine reprocessed, packaged instruments of the type Coagulation Shear were included in the examination, which resulted in identification of residual contamination on eight items. Two instruments were definitely, another one probably, identified as damaged (Fig. 8). In many cases contamination could be observed by visual inspection. This applies mainly to blade, jaw, and pull wire, which are located on the distal end of the instruments. Several locations, where contamination could not be observed macroscopically, were clearly identified as contaminated using SEM. Partly due to the red color of the contamination observed and the identification of nitrogen and the C=O double bonds, the contamination were considered to be residues of blood, fibrin, or macroalbumin.

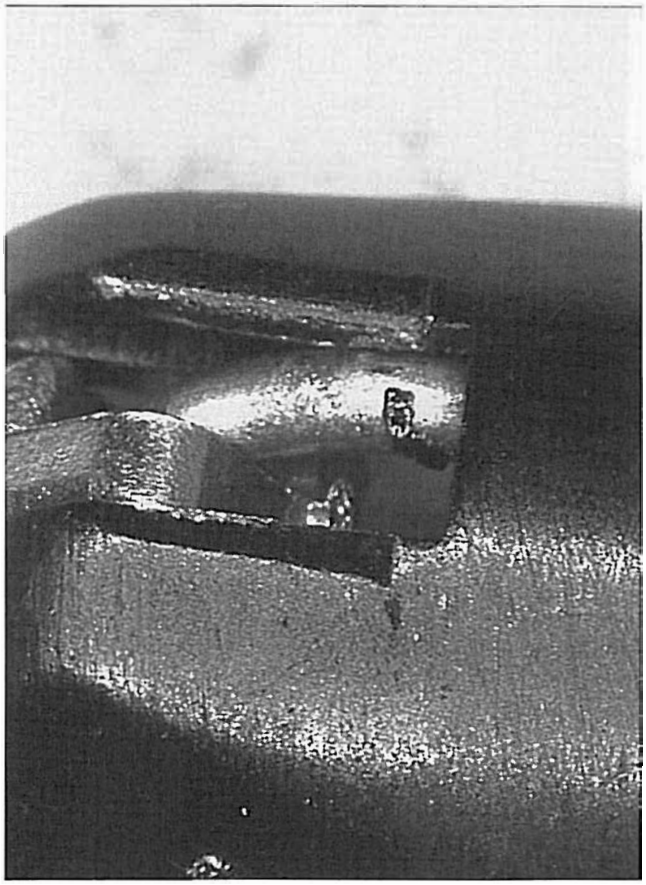

Fig. 5. Material inside the hinge of a reprocessed single-use device.

Discussion

The results of our investigation demonstrate high similarity to those of a previous study, performed with single-use and reusable accessories for flexible endoscopes [14, 20]. Both studies suggest that disposable devices are not successfully decontaminated using current policies for reprocessing and may suffer material destruction during these procedures. Although this study did not attempt to find a direct correlation between poorly decontaminated devices and occurrence of disease, our results do not exclude such a causality. Residual bioburden on insufficiently cleaned devices may hamper disinfection as well as sterilization procedures, and may account for nosocomial infection [6]. The cell walls of either viable or inactivated bacteria in residual material may release lipopolysaccharides with pyrogenic activity [19], exposure to which could result in unanticipated or as yet unknown immunogenic effects in subsequent patients. Furthermore, microorganisms enclosed in organic or inorganic material (e.g., crystals) are protected from sterilizing agents, particularly from EtO [3]. Of particular concern is the risk of transmission of

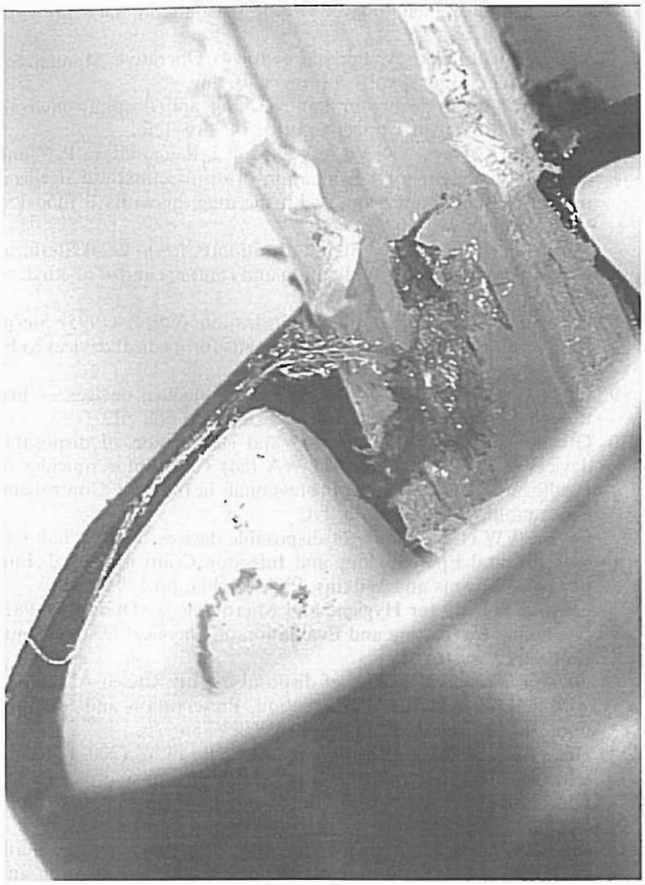

Fig. 6. Remaining tissue inside a reprocessed Harmonic scalpel, close to the hinge.

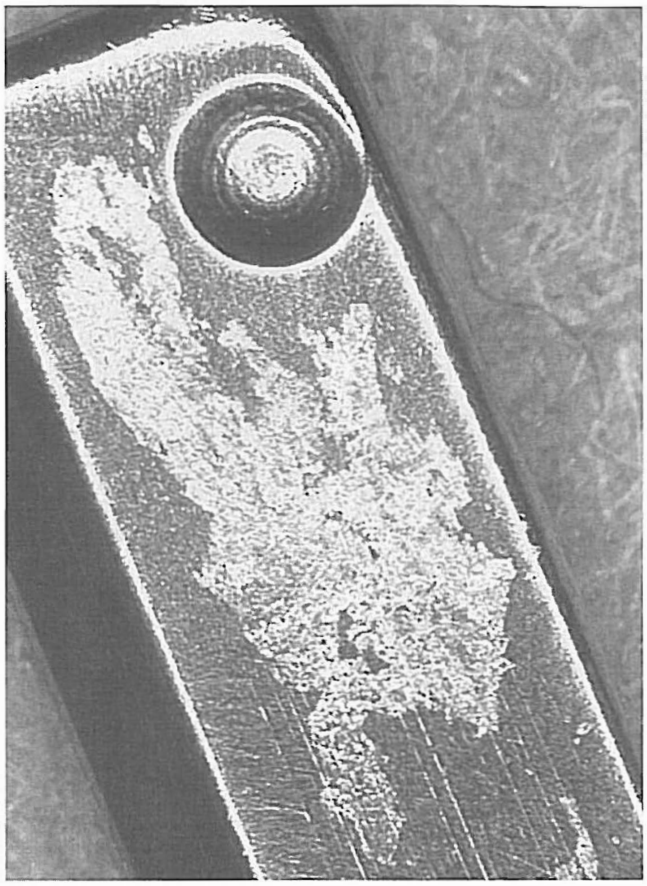

Fig. 7. Protein material on a plane surface of the blade of a Harmonic scalpel after reprocessing. The device was declared to be ready for use in the next patient.

proteinaceous infectious particles (prions), which demonstrate a higher level of resistance to sterilization than any other pathogenic agent including the organisms used in this study.

As anticipated, differences in the materials and design of single-use devices may have impaired the effectivity of cleaning, disinfection, and sterilization. The single-use 5 mm Harmonic scalpel showed contamination after cleaning distributed over a longer distance than before cleaning. This finding indicates that the cleaning agent penetrates into the device and dilutes soluble blood components. However, the design of the device prevents flushing out of the dissolved substances, which remain during subsequent applications on patients.

The physical design of the monopolar scissor DCS 12 and the harmonic scalpel LCS 5 K, however, allowed a thermal disinfection process destroying most of the microorganisms but prevented the complete removal of the contamination during the washing process. If the design of a device does not allow access for either the cleaning or disinfection agents, reprocessing will very likely fail [2, 3, 6, 15]. We believe that the tested single-use devices could not be decontaminated successfully, because the structure of the device prevents contact between cleaner or disinfectant and the inner surfaces of the instrument. Finally, the results of the laboratory tests were confirmed by the results gained from the clinically used devices.

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

Using current standards for cleaning, disinfection, and sterilization, none of the reprocessed single-use instruments was suitable for use in humans. Disinfection and sterilization of disposable instruments could not be performed to required levels, and this may provide an opportunity for survival and growth of nonresistant or nosocomial pathogens. Reprocessing procedures may result in materials changes, which add to the degradation and reduced functional integrity of these devices. If cleaning of 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 occur as a result of residual contamination. When reprocessing is performed, routine monitoring of internal cleanliness and sterility should be mandatory for reprocessing methods. This

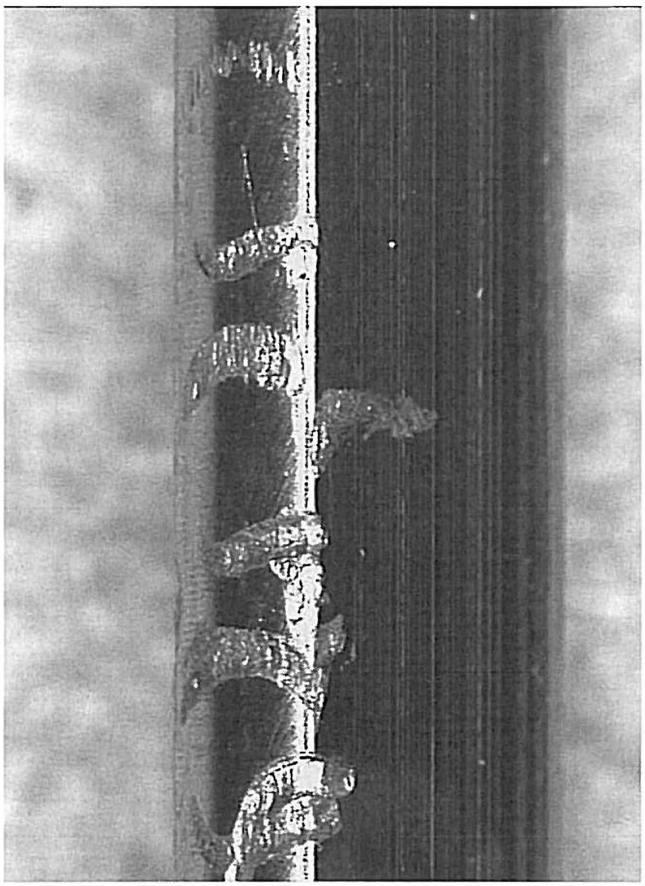

Fig. 8. Damage on a blade of a Harmonic scalpel.

study may help to identify devices which should not be considered for reprocessing because their structure does not allow access to all surfaces for cleaning and sterilization.

References

1. Association for the Advancement of Medical Instrumentation (AAMI) (1994) Good hospital practice: Steam sterilization and sterility assurance. ANSI/AAMI ST 45–1993
2. Association for the Advancement of Medical Instrumentation (AAMI) (1994) Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers. AAMI TIR No. 12. Arlington VA
3. Bond WW (1998) Endoscope reprocessing: problems and solutions. In: Rutala WA (eds) Disinfection, Sterilization and Antisepsis in Healthcare. Association for Professionals in Infection Control and Epidemiology (APIC), Washington, DC, pp 151–163
4. Buess G, Cuschieri A, Perissat J (1994) Operative Manual for Endoscopic Surgery, vol 1. Springer, Berlin
5. CDC (1985) Guideline for handwashing and hospital environmental control. Am J Infect Control 14: 110–126
6. Chaufour X, Deva AK, Vickery K, Zou J, Kumaradeva P, White GH, Cossart YE (1999) Evaluation of disinfection and sterilization of reusable angioscopes with the duck hepatitis B model. J Vasc Surg 30: 277–282
7. European Committe for Standardization (CEN) (1994) Sterilization of medical devices. Validation and routine control of ethylene oxide sterilization. EN 550
8. European Committee for Standardization (CEN) (1995) Sterilization of medical devices. Requirements for medical devices to be labelled sterile. EN 556
9. Greene VW (1986) Reuse of disposable medical devices — historical and current aspects. Infect Control 7: 508–513
10. Greene VW (1995) Disinfection and sterilization of disposable devices/equipment. In: Rutala WA (ed) Chemical germicides in Healthcare. Association for Professionals in Infection Control and Epidemiology, Washington, DC
11. Greene VW (1999) Reuse of disposable devices. In: Mayhall CG (ed) Hospital Epidemiology and Infection Control, 2nd ed. Lippincott, Williams and Wilkins, Philadelphia, pp 1201–1208
12. German Society for Hygiene and Microbiology (DGHM) (1981) Guidelines for Testing and Evaluation of Chemical Disinfectants. G. Fischer, Stuttgart
13. Hanlon GW (1998) Reuse of disposables. In: Russell AD, Hugo WB, Ayliffe GAJ (eds) Disinfection, Preservation and Sterilization, 3rd ed. Blackwell, Oxford, pp 777–786
14. Heeg P, Roth K, Reichl R, Cogdill P, Bond W (2001) Decontaminated single-use devices: an oxymoron that may be placing your patients at risk for cross-contamination. Infect Contr Hosp Epidemiol 22: 542–549
15. International Standardization Organiszation (ISO) (1994) Sterilization of healthcare products. Requirements for validation and routine control. Industrial moist heat sterilization. ANSI/AAMI/ISO 11134
16. International Standardization Organization (ISO) (1999) 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
17. Mayhall CG (1986) Types of disposable medical devices reused in hospitals. Infect Control 7: 491–494
18. Reichl R, Beckmann P, Dreher WL, Inacker O, Mueller E, Heeg P, Roth K, Buess G (1998) Innovations in medical technology based on surface and interface analytical methods (part 1). Zentr Steril 6: 222–231
19. Rolansky PF, Dawson ME, Novitsky TJ (1991) Plastics, endotoxins and the LAL test. J Parent Sci Technol 45: 83–87
20. Roth K, Heeg P, Reichl R, Cogdill P, Bond W (1999) Quality assurance on reprocessing accessories for flexible endoscopes — just how clean are cleaned instruments really? Zentr Steril 7: 84–96
21. Schrimm H, Sieber JP, Heeg P, Roth K, Mueller-Schauenburg W, Keller KD, Buess G (1994) A new method for validating and verifying the cleaning of tubular instruments. Zentr Steril 2: 313–324
22. Woolard K (1996) Reuse of single-use medical devices: who makes the decision? Med J Aust 164: 538