List of Titles

Technical Information Report

AAMI TIR30:2003

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

AAMI
Association for the Advancement of Medical Instrumentation

AAMI Technical Information Report AAMI TIR30:2003

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Approved 8 October 2003 by
Association for the Advancement of Medical Instrumentation

Abstract: This report is intended as a resource for manufacturers of medical devices who must validate the instructions for reprocessing that they include with their devices. In addition to describing available processes, materials, test methods, and acceptance criteria for cleaning medical devices that are labeled by the manufacturer for reuse and reprocessing, the report also discusses some of the underlying problems and challenges associated with validating a cleaning method. Extensive references and an annotated bibliography on device design also are included.

Keywords: device design, materials compatibility, test soil

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International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
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ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical

International designation	U.S. designation	Equivalency
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
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ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

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Association for the Advancement of Medical Instrumentation

Cleaning of Reusable Medical Devices Working Group

This technical information report was developed by the AAMI Cleaning of Reusable Medical Devices Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily mean that all working group members voted for its approval.

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Foreword

This technical information report (TIR) was developed by the AAMI Cleaning of Reusable Medical Devices Working Group under the auspices of the AAMI Sterilization Standards Committee.

Manufacturers of reusable medical devices must provide validated cleaning instructions with their products in order to comply with U.S. Food and Drug Administration (FDA) regulations and, more importantly, to ensure that their products can be properly cleaned and sterilized in health care facilities and other facilities that reprocess medical devices.

The objective of this TIR is to provide to medical device manufacturers information on the cleaning agents and methods available in health care facilities and other facilities that reprocess medical devices, and to review the published literature on test soils, test methods, and acceptance criteria that can be used in validating cleaning instructions for reusable medical devices.

A fundamental problem that exists with the creation of any document of this type is its relevancy and utility after it has been published. The development of a new class of medical device or cleaning agent or the emergence of an extremely hardy pathogen could cause enough of a change to invalidate cleaning processes that previously had been used with acceptable results. To address this problem, an attempt has been made to systematically define and categorize the underlying problems and challenges that cleaning processes, test soils, and test methods must overcome to yield a validated cleaning process.

At least two underlying problems have prompted the creation of this document. The first is a significant increase in the complexity of the medical devices being manufactured today, with the result that they have become considerably harder to clean. Generally, the complexity of validated cleaning procedures will be proportional to the complexity of the medical devices for which they are designed. Second, new pathogens (e.g., prions, hepatitis C, antibiotic-resistant microorganisms) continue to emerge; in addition to the natural selection processes that cause these species to emerge, one must now consider the possibility of bioterrorism and the development of organisms specifically created to resist cleaning and sterilization practices.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

Introduction

Medical devices, as defined by the U.S. Food, Drug, and Cosmetic Act (21 USC 301); the Medical Device Amendments of May 28, 1976; and subsequent amendments—and as regulated by the U.S. Food and Drug Administration (FDA)—range from simple wooden tongue-depressing blades to complex and sophisticated electronic equipment such as magnetic resonance imaging (MRI) and proton emission tomographic (PET) equipment. Diagnostic test kits are also included within the device definition. Devices may be applied to the surface of the body; be inserted into an orifice or through the skin; or find their way into the tissues, spaces, or organs of the bodies of humans or animals by ingestion, inhalation, skin absorption, or implantation. Devices may contact blood, mucosal tissue, muscle or other connective tissue, adipose tissue, bone, teeth, and other tissues, and may remain in contact for short time periods or for up to a lifetime. Devices are used for a wide range of diagnostic and therapeutic applications within the medical, dental, and veterinary fields, including a variety of surgical and life-saving applications. Devices are also used to administer various medicines, drugs, vaccines, biologicals, and nutritional supplements. Certain products (such as prefilled syringes) are considered combination drug–devices.

Manufacturers of reusable medical devices must provide instructions on how to reprocess their devices between patient uses. Two types of risks are associated with the reuse of a medical device: (a) the risk of disease transmission from one patient to another or from environmental sources to a patient; and (b) the risk of inadequate or unacceptable device performance following reprocessing. Reprocessing involves several steps, including cleaning, testing for device performance, and disinfection and/or sterilization.

Cleaning a device is the critical first step in reprocessing any device after it has been used on a patient. Failure to remove foreign material (e.g., soil, organic and inorganic materials, lubricants, microorganisms) from both the outside and the inside of the device can interfere with the effectiveness of subsequent disinfection and/or sterilization. Cleaning is normally accomplished by manual wiping, brushing, or flushing or by using mechanical aids (e.g., ultrasonic cleaners, washer-decontaminators, washer-sterilizers) in conjunction with water and detergents to remove foreign material.

In the past, a device was considered “clean” if the person who was performing the cleaning task observed no visible foreign material. Today, however, many devices have long or narrow opaque lumens, crevices, hinges, acute angles, serrated edges, junctions between insulating sheaths, coils, or other designs that make it difficult or impossible to rely on the traditional visual endpoint. In addition, visual observation might not be adequately sensitive to detect levels of soil that could interfere with subsequent reprocessing.

There are few tests that can be used to validate cleaning. To validate cleaning of a given device, one must have a test soil and a quantitative test method for detecting residual soil after cleaning. If validated cleaning protocols were available today, they could help ensure that adequate cleaning is accomplished and a device can be reliably disinfected and/or sterilized before it is used on the next patient.

The manufacturer must validate the instructions for reprocessing a reusable device before marketing it. In addition, manufacturers must consider

a) that exposure to chemicals, such as cleaning agents, could change the material used in the device;

b) whether the materials of construction will absorb or adsorb chemical agents, which could then gradually leach from the material over time; and

c) how cleaning processes could affect the function of the device.

This compendium of processes, materials, and test methods for cleaning reusable medical devices is meant to provide device manufacturers with information to facilitate the validation of cleaning processes to be used for their reusable medical devices.

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

1 Scope

1.1 General

This technical information report (TIR) is a compilation of available information regarding test protocols, test soils, and acceptance criteria that can be used by medical device manufacturers to validate cleaning processes for reusable medical devices.

1.2 Inclusions

This TIR covers the validation of cleaning processes for medical devices that are intended and labeled by the manufacturer for reprocessing and reuse. Such devices include those that are intended for routine reprocessing and reuse (e.g., surgical instruments) and certain implant accessories (e.g., orthopedic screws) that are provided as parts of sets and are intended and labeled by the manufacturer for reprocessing if not used during a particular procedure.

Included within the scope of this TIR are the following topics:

a) device design and material considerations;

b) available cleaning processes;

c) test soils;

d) test methods;

e) test equipment;

f) acceptance criteria; and

g) regulatory considerations.

This TIR also provides references and an informative annex.

1.3 Exclusions

This TIR does not cover the performance of procedures for cleaning reusable medical devices in health care facilities, nor does it cover procedures for reprocessing single-use medical devices and hemodialyzers in health care facilities. For information on these topics, see ANSI/AAMI ST35:2003, FDA (2000b), and ANSI/AAMI RD47, respectively.

NOTE—The test protocols, test soils, and acceptance criteria described in this TIR do not necessarily apply to the validation of cleaning processes for medical devices contaminated with prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD), and thus such devices may require specialized processing steps. For information regarding the decontamination of devices exposed to prions, see AORN (2003), Favero and Bond (2001), and Rutala and Weber (2001), as well as the recommendations of the Centers for Disease Control and Prevention <http://www.cdc.gov/ncidod/hip/INFECT/Cjd.htm>, the American Society for Health Care Central Service Professionals <http://www.ashcsp.org>, and the International Association of Healthcare Central Service Materiel Management <http://www.iahcsmm.com>.

2 Definitions, abbreviations, and symbols

2.1 bioburden: Population of viable microorganisms on a product and/or a package.

2.2 biocompatibility: Lack of an adverse health effect from exposure of a biological system to materials from which a device is made.

2.3 biofilm: Accumulated biomass of bacteria and extracellular material that adheres tightly to a surface and cannot be removed easily (Donlan, 2002).

NOTE—Some microscopic organisms have the ability, when growing in water or water solutions or *in vivo* (e.g., the bloodstream), to adhere to a surface and then exude over themselves a polysaccharide matrix. The matrix contains cells, living and dead, as well as polysaccharide (sometimes referred to as *glycocalyx*) and prevents antimicrobial agents such as sterilants, disinfectants, and antibiotics from reaching the microbial cells.

2.4 cfu: Colony-forming units.

2.5 cleaning: Removal of contamination from an item to the extent necessary for further processing or for intended use.

2.6 decontamination: According to the Occupational Safety and Health Administration (OSHA), "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal." (29 CFR 1910.1310)

NOTE—The term is generally used in health care facilities to refer to all pathogenic organisms, not just those transmitted by blood.

2.7 disinfection: Destruction of pathogenic and other microorganisms by thermal or chemical means.

NOTE—Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores). Disinfection processes do not ensure the margin of safety associated with sterilization processes.

2.8 material safety data sheet (MSDS): Document specifying the properties of a material, its potential hazardous effects on humans and the environment, and the precautions necessary to handle and dispose of the material safely.

2.9 materials stability: Ability of a material to resist physical degradation (e.g., wear, particle formation, cracking, crazing, breaking) and/or chemical degradation (e.g., production of toxic chemicals, color change, opaqueness) that could affect the safety and effectiveness of the device.

2.10 medical device: Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiological process; or
- control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

2.11 microorganism: Entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size.

2.12 prions: Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle, and Creutzfeldt-Jakob disease (CJD) in humans.

NOTE—Prions are unlike any other infectious pathogens, including viruses, because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prion diseases are disorders of protein configuration involving template-assisted replication and resulting in abnormal protein accumulation in the brain, which causes neuronal dysfunction, degeneration, and death. Prions are extremely resistant to inactivation by heat and disinfecting agents (Baron, et al., 2001).

2.13 reprocess: To make ready for reuse a device, instrument, or piece of equipment by any or a combination of the following processes: cleaning, decontamination/disinfection, repackaging, and sterilization.

2.14 reusable medical device: Device intended for repeated use on different patients, with appropriate decontamination and other processing between uses.

2.15 SDS: Sodium dodecyl sulfate.

2.16 sterilization: Validated process used to render a product free from viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item may be expressed as a probability. Although that probability may be reduced to a very low number, it can never be reduced to zero.

2.17 test soil: Formulation designed as a substitute for clinical soil or debris typically found on a medical instrument after clinical use and used as part of the procedure to validate a cleaning process.

2.18 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

2.19 verification: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process has met predetermined specifications.

3 Device materials

3.1 Overview

The materials from which a device is fabricated affect the types of cleaning, disinfection, and sterilization processes that can be used to reprocess the device safely and effectively without adversely affecting device function.

3.2 Types of materials

Most reusable medical devices are composed of metallic and/or polymeric materials. Table 1 provides examples. A comprehensive list of materials found in medical devices is provided in EN 12011.

Table 1—Examples of reusable medical devices

Material	Examples
Metallic materials	Surgical instruments (e.g., hemostats, vascular clamps, drill bits)
Polymeric materials	Endoscopes, respiratory masks

3.3 Changes in materials and their surfaces produced by reprocessing

Reusable medical devices generally are disinfected and/or sterilized before they are used. Adequate cleaning is required before a device is disinfected or further processed. A wide variety of chemicals and processes can be used for cleaning devices. The effects of these chemicals and processes on the device should be examined carefully.

The surfaces of many materials can be significantly (and irreversibly) altered by various processing activities. Chemical reactions such as oxidation, alkylation, amidation, and reduction can occur. Extraction ("leaching") of various chemical species (including low-molecular-weight polymers; monomers; short-chain, uncrosslinked, or cyclic material; and plasticizers or other additives) from polymers can occur. Metals can weaken, become dull, or rust. Crazing (i.e., the development of very fine surface cracks) and other changes in the physical (including thermal, electrical, mechanical, optical, rheological, and viscoelastic), chemical, and/or biological properties can result from such surface-modifying processes (Page and Glaser, 1990). Changes can involve swelling or solubilization of the surface of a device, stickiness and increased tackiness, increased membrane permeability or porosity, crazing, accelerated wear of the polymer (often accompanied by the generation of many undesired particles), degradation, or depolymerization, all of which could result in a premature, total breakdown of the material. Other effects on devices can include adhesive failure, joint and seam failure, and delamination of polymer coatings (Glaser, 1993). The effects of reprocessing on device materials can lead to total breakdown or loss of functionality from reduced tensile strength and/or loss of flexibility.

It is generally recognized that the surface properties of a material can significantly affect its biocompatibility, protein-binding ability, membrane selectivity, hydrophilicity (i.e., "wettability"), hydrophobicity, lubricity, chemical barrier properties, and bonding and associative properties. Surface properties also affect the thermodynamic property of surface-free energy of a device, its reflectivity and other optical properties, corrosion and wear resistance, cellular transport properties, and catalytic nature, as well as the amount of mineral deposition and encrustation, and the retention of static charge (Glaser, 1993).

Changes such as those listed above can adversely affect the safety of the device and its effectiveness. It is also possible that residues of the cleaning agent could remain in or on the device. In addition, a chemical reaction of the cleaning agent with the device could take place, producing byproduct.

Residues of the cleaning process can produce electrical charges on the surface of certain materials. Those residues might be caused by the process itself or by another mechanism. Such electrical charges (sometimes referred to as "static electrical charges") can attract or repel other particles such as dust and dirt to or from the surface of the device.

As noted earlier, the modification of a device surface can affect a number of the device's properties, including its protein-binding ability and the way certain cells adhere to its surface (i.e., bio-adhesion). Examples of deliberate modification of device surfaces include antimicrobial coatings and treatments. One of the disadvantages or complications of a surface treatment is the potential alteration or removal of a desired coating (such as a nonthrombogenic coating) by a later process, such as cleaning.

3.4 Selection of materials

3.4.1 General considerations

The selection of a material from which a device is to be constructed involves a number of important considerations, including the

a) suitability of the material for the intended application;

b) physical, chemical, and biological stability of the material;

c) cost and availability of the material;

d) "workability," "machineability," and "formability" of the material; and

e) ability of the material to be cleaned, decontaminated, disinfected, and/or sterilized (as appropriate and if necessary).

It should be noted that design and engineering considerations (see section 4) strongly affect the selection of device materials.

3.4.2 "Cleanability" considerations

The following considerations related to the "cleanability" of certain types of devices (e.g., hand-held surgical instruments, flexible fiberoptic endoscopic equipment) affect the selection of device materials (Glaser and Schultz, 1997):

a) Certain types of "stainless" steel tend to exhibit discoloration and oxidation when subjected to aqueous chloride ion or chlorine-releasing chemicals (e.g., chloramines) in the water supply. Stainless steel also can be subject to pitting and stress corrosion cracking.

b) Many polymeric materials and synthetic organic materials are thermolabile and cannot be subjected to elevated temperatures.

c) Most latex elastomers are difficult to clean, lose their elasticity, and suffer degradation of physical properties when subjected to many types of cleaners.

d) Most polymeric membranes and capillary fibers are adversely affected by certain types of cleaners.

e) Certain types of coatings are altered and/or removed by exposure to many types of cleaners.

f) Many lubricants essential for the smooth operation of certain devices are easily removed by the action of cleaning agents.

g) Certain types of medical equipment (e.g., devices containing lenses and/or mirrors) cannot be fully immersed in aqueous solutions because adhesives used with the optics cannot be immersed.

h) Some types of endoscopic equipment cannot be immersed in aqueous cleaning liquids because of the inadvisability of exposing the illumination and/or electronic components to water.

i) Most video cameras and many still cameras (and other photographic equipment) are not designed to be immersed in liquid and, therefore, are difficult to clean and disinfect properly.

j) Certain aggressive cleaning solutions (e.g., solutions containing concentrated aqueous sodium hydroxide or concentrated aqueous sodium hypochlorite, which are required when working with prions) are extremely destructive to most instruments and materials.

4 Device design

4.1 Overview

The design of a reusable medical device is a particularly important factor in assessing the variables affecting the effectiveness of a cleaning process, whether it is a manual process or an automated process. Devices must be designed not only to meet end-user needs from a functionality standpoint, but also with consideration for their eventual reprocessing. The safety and effectiveness of the reprocessed devices are points of focus, but also of substantial importance is the cleanability of the devices. Several publications, as well as related guidance documents and conferences,[1] have reported studies and highlighted the close relationship between the design of devices and the results of the cleaning process application (see Annex A).

This section describes design features that render devices difficult to clean and design considerations that can help improve the cleanability of a device. Device designers should seriously consider such information so that the devices that they develop are easier to clean and reprocess.

4.2 Design features offering difficulty in cleaning

The following design features and types of devices pose challenges in the cleaning process:

— Long, narrow (≤ 1 mm diameter) lumens and channels (particularly flexible designs)

— Multiple internal channels

— Channels that are not freely accessible

— Valves

— Crevices, joints, or surface pores

— Elevator wire channels in side-viewing duodenoscopes

— Close-fitting, metal-on-metal fittings with very close tolerances

— Clamps that cannot be opened for cleaning

— Forceps that cannot be readily dismantled (e.g., arthroscopy forceps)

— Rough, irregular, discontinuous surfaces that can entrap or retain bioburden and impurities

— Capillary gaps

— Forceps not designed for cleaning of their internal lumens

— Hinges, depressions, or joints with gaps, as well as ribbed or otherwise “roughened” surfaces (e.g., jaws)

— Porous materials (smooth surfaces are desirable, where possible)

— Luer locks

— Rongeurs

— Junctions between insulating sheaths and activating mechanisms (as in certain laparoscopic instruments)

— Articulations and grooves of forceps

— Overlapping or butted joints that create inferior angles formed by two meeting walls

— Dead-headed flow parts and/or small fluid channels

— Sharpness of the cutting edge

[1] For example, the 1992 FDA Conference, Infection Control Symposium: Influence of Medical Device Design; the 1996 AAMI/FDA Conference on Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities; and the 1997 AAMI/FDA Conference on Reprocessing Medical Devices: Designing, Testing, and Labeling.

4.3 Design considerations

Devices should be specifically designed for reprocessing, and the design should allow access for suitable cleaning. Soaking and flushing are often not enough to remove all debris, especially from items that have sticky, dried-on organic matter acquired during lengthy procedures. Ease of disassembly of multicomponent devices is important because disassembly allows thorough cleaning. Ease of reassembly is also important; otherwise, the user could break the device, lose parts, or be reluctant to disassemble it. Consequently, the following aspects of device design should be considered:

— All surfaces, both interior and exterior, should be accessible to cleaning agents and brushes.

— Luer locks and luer slips should be designed to be taken apart easily for cleaning, and the device should be designed so that luer locks and luer slips will not be in contact, directly or indirectly, with patient tissue (e.g., blood or other body fluids).

— There should be free area inside the shaft of minimally invasive surgery (MIS) devices. MIS devices should be able to be disassembled for cleaning, so that the lumen can be thoroughly brushed.

— Smooth surfaces are easier to clean. Therefore, to the extent possible, device designers should avoid surface roughness, transitions, niches, slots, recessed channels, grooves, and the like.

— User needs, the environment in which the device will be used, and how the user interacts with the device should be taken into account.

— Materials and adhesives should be compatible with cleaning and reprocessing agents. Materials that scratch easily or are prone to corrosion, including rusting, should be avoided.

— Reprocessing methods for endoscopic tubing should be designed to avoid treatment by chemical fixatives and subsequent drying, since these are two major factors that limit effective cleaning.

— Attachments that cover surfaces should be removable.

— Electrical buttons should be of a membrane panel type.

— Mechanisms that slide over other parts should be “opened up” to allow adequate clearance.

— The surface area around fastening devices of hinged joints should be reduced or eliminated.

— Stopcocks should be designed out or be possible to dismantle.

— Strain-relief boots should be sealed at the cable junction and tapered down to the cable diameter.

— Ball detents or securing methods should be designed to allow for ease of decontamination.

— Deep and/or small crevices and fissures should be avoided.

— Device features that are shaped like cups or have cup-like features should be avoided if they do not serve a functional purpose.

— Acute angles and rough, porous, or occluded surfaces should be eliminated.

— Flushing ports and take-apart models facilitate cleaning.

— Shrink tubing and coats can crack and harbor soil.

— Serrations and other cuts in metal should be accessible.

— Joints and lumens should be minimized to the extent possible, and/or accessible.

— There should be a smooth transition between meeting walls.

— Overlapping, tightly fitted contact areas should be able to be taken apart and easily reassembled.

— Tightly coiled metal configurations (e.g., forceps used with flexible endoscopes) should be avoided, if possible.

— Adverse flow conditions within an instrument and internal flow restrictions should be minimized.

— It should be possible to irrigate all of the lumens under positive pressure, and there should be defined outlets for selective irrigation of functional components. If this is not feasible, the device should be designed so that it can be disassembled for cleaning.

— Surface topology and biological adhesiveness (proteins, microorganisms) should be considered.

— Motorized equipment can entrap debris.

4.4 Bibliography

An annotated bibliography of the literature pertaining to device design and cleanability is provided in Annex A.

5 Available cleaning processes

5.1 Overview

To be of value to both manufacturers and end users, medical device cleaning processes defined and recommended by device manufacturers must be capable of being implemented efficiently in the health care facility. To assure users that a device can be cleaned successfully, device manufacturers should develop recommendations that

a) provide for thorough cleaning with a fully validated process;

b) can be performed in health care facilities using commonly available cleaning agents, equipment, and methods;

c) can be performed consistently by health care personnel; and

d) are consistent with professional recommendations and with OSHA regulations for minimizing occupational exposure to bloodborne pathogens and toxic chemicals.

This section discusses cleaning agents, equipment, and procedures that are commonly used in health care facilities. ANSI/AAMI ST35 provides further information on decontamination, including cleaning processes recommended for health care facilities.

5.2 Cleaning agents

5.2.1 General considerations

Cleaning agents are materials used to remove soil (organic, inorganic, and biological matter) from medical devices so that they can be further processed for their final intended use (Spaulding, 1968). Such materials include items used for the physicochemical removal of soils by wiping, brushing, or flushing with fluids (e.g., detergents with enzymes) that facilitate the cleaning process.

In choosing cleaning agents for use in a validated cleaning process, the agent should be compatible with the materials used in the medical device to be cleaned and with the materials used in the cleaning equipment itself. For example, the chemicals should not cause corrosion in ultrasonic cleaning equipment, washer-disinfectors, or washer-sterilizers, and they should not promote electrolytic action between the equipment and the medical devices being cleaned. In addition, any chemical should be easy to remove from the medical device by rinsing with readily available water of defined properties, so that the device does not retain residual chemicals in amounts that can harm humans, damage the device, or create other hazardous situations. It should also be noted that the use of elevated temperatures (higher than those recommended by the manufacturer of the cleaning agent) in a cleaning process will cause denaturation and precipitation of the soil components (e.g., blood) and make them even more difficult to remove. An ideal cleaning agent

a) is nonabrasive,

b) has low foam,

c) is able to be free-rinsed,

d) is biodegradable,

e) provides for rapid soil dispersal or salvation,

f) is non-toxic,

g) is effective for all types of soil,

h) has a long shelf life,

i) is cost-effective, and

j) provides for monitoring its effective concentration and/or use life.

5.2.2 Enzyme products

Enzyme products are commonly used in the processing of difficult-to-clean devices such as vascular instruments, instruments with hinges, microinstruments, and instruments with lumens (e.g., flexible endoscopes). Most product lines of instrument cleaners include an enzymatic product. Four distinct types of enzymes are used in enzymatic detergents, and each is specific to a certain component of surgical soil and ineffective on other components (Table 2). Proteases break down proteins, lipases break down lipids, amylases break down starch, and cellulases break down carbohydrates. Enzymatic cleaners incorporate at least one of these four types of enzymes in their formulation, and a few use two, three, or all four types. Much of the soil found on medical items is made up of proteins, lipids, and carbohydrates, which can effectively shield or encapsulate other soil components to prevent their removal from the surfaces of the medical device. Enzymes break down or "digest" these large organic molecules, facilitating their removal. The detergent portion of the enzymatic cleaner solubilizes the digested material and other soil components such as inorganic salts.

The amount of soil and level of soil dehydration can inhibit the removal of soil components from surfaces. Because the soil components are substrates for the enzymes and the enzymes gradually degrade during use, the amount of soil on the device during the enzyme treatment will affect the efficiency of cleaning. Also, enzymes work best under fairly narrow conditions. Among the requirements for optimal enzymatic activity are high water concentrations. If the soil is dried onto the device, the soil must be rehydrated before the enzymes can be effective. Rehydration is time-dependent and will limit the enzyme-soil contact time. For these reasons, precleaning and preventing the devices from drying is very important. Moreover, enzymatic detergents have an optimal temperature range in which they are effective. If they are used under conditions outside of this range (colder or hotter), their effectiveness will be reduced. Also, the enzymes in these cleaners are used up as they "digest" the soil and thus must be replenished or replaced for every cleaning procedure, according to the manufacturer's instructions.

In addition to detergents and enzymes, typical commercial enzymatic cleaning solutions contain buffering agents to help maintain the cleaning solution at an optimal pH range for the enzymatic and detergent activities.

Table 2—Types of enzymes used in enzymatic cleaners

Enzyme	Soil component	Product	Source of soil component
Proteases	Proteins, oligopeptides, peptides	Endopeptides and exopeptides	Animal, plant, microbial
Lipases	Acylglycerols	Glycerol esters	Animal, plant, microbial
Amylases	Starch, glycogen	α(1-4) and α(1-6) D-glucose	Animal, plant, microbial
Cellulases	Cellulose	β(1-4) D-glucose	Plant

5.2.3 Detergents

Detergents are generally used for cleaning medical devices. Detergents are any of a group of synthetic, organic, liquid, or water-soluble powders containing wetting and emulsifying agents that suspend soil and prevent the formation of insoluble compounds or scum on the device or the surface of the cleaning solution. Detergents with neutral pH (7) are generally recommended for cleaning surgical instruments because metal surfaces can be damaged by harsher pH conditions (either acid or alkaline). However, a neutral-pH detergent does not necessarily provide good cleaning. Some types of automatic washer-decontamination equipment (see 5.3.3) use a detergent of higher pH (8 to 11), followed by rinsing with a neutralizing agent. There are also detergents that function in the acidic pH range that are used for manual cleaning. Thorough rinsing with water is necessary to protect instrument surfaces from damage at these pH extremes.

Detergents have been formulated for use in specialized applications (e.g., ultrasonic cleaners, hard water). Some detergents may form precipitates in the presence of hard water, in which case hard-water cleaning formulations should be used. Detergents also must be compatible with the cleaning equipment with which they are used. For example, a foaming detergent might hinder the operation of a washer-disinfector that uses high-pressure jets. In addition, cleaning chemicals should be compatible with other chemicals used in the same process stage and those used in previous and subsequent stages (such as disinfection), to minimize the adverse effects of any carryover.

5.2.4 Detergent-disinfectants

Detergent-disinfectants combine detergent-type cleaning agents with a chemical disinfectant. The use of detergent-disinfectants usually involves a multistep process. Like all disinfectant solutions, a detergent-disinfectant must be in contact with the microorganisms for sufficient time to achieve microbial kill. The required exposure should be specified in the product labeling.

5.2.5 Rinsing

Adequate rinsing is necessary to remove all traces of detergents and residual soil. Water quality should be considered when developing and testing cleaning procedures. Some health care facilities use filtered water systems in Central Service; however, tap water is the most common rinsing agent. Water hardness, temperature, and the type of soil can affect the effectiveness of detergents and, consequently, the effectiveness of the cleaning process. Water particulates (i.e., hardness) vary from one area to another and from season to season within the same area. If water quality analysis shows that water quality affected the cleaning process during validation, the results should be available for review by the prospective device user. The device manufacturer should provide comprehensive instructions for rinsing that describe the type and quality of the rinse water and the volume and duration of the rinse.

Rinsing aids, generally containing surfactants, are often used in conjunction with washer-disinfectors to enhance removal of salt deposits that can form when hard water is used in the cleaning process.

5.2.6 Assessment of cleanliness and residuals

Information about laboratory methods that can be used to quantify residual concentrations of cleaning products and acceptable residual levels might be available in the scientific literature or from the manufacturer or supplier of the cleaning chemicals. The sensitivity of the method should be sufficient to determine the presence of chemical components of the cleaning product at concentrations *below* the levels at which adverse physical/chemical effects on devices or biological effects on patients could occur.

5.2.7 Additional processing

After devices are rinsed, they are visually inspected for cleanliness and working condition and then dried to remove residual fluids. Water droplets remaining on a device provide favorable conditions for microbial growth and survival, inhibit ethylene oxide and other sterilization processes, dilute liquid chemical disinfectants/sterilants, and/or can cause rusting or spotting of device surfaces. Surgical instruments with moving parts, hinges, and box locks might require lubrication. If lubrication is necessary, it is common practice either to immerse instruments for a few moments in a water-soluble lubricant solution or spray them with a water-soluble lubricant solution. After being removed from the lubricant, instruments are allowed to air-dry or are dried by hand or forced air. Silicone- or oil-based lubricants are not recommended because sterilants cannot penetrate these lubricants, which coat the microorganisms and thus inhibit disinfection or sterilization.

5.3 Cleaning methods

5.3.1 General considerations

In general, cleaning methods can be divided into two categories: manual and mechanical/automated. Each category has advantages and limitations that should be considered when establishing a validated cleaning process.

Manual cleaning methods are limited by variations among the individuals doing the cleaning. Despite validated procedures, the failure of individuals to follow the procedures or unforeseen variations in the procedures can reduce cleaning effectiveness. Such variations are continuing challenges to the maintenance of any validated process that involves manual labor (see 5.6). Comprehensive, step-by-step instructions will assist immeasurably in reducing variations in how validated procedures are performed.

Automated cleaning methods are advantageous because they are performed by machines and thus are repeatable, reproducible, and more easily validated. From the user's standpoint, automated cleaning methods minimize the exposure of personnel to harmful microorganisms and chemicals, provide reproducible levels of cleaning effectiveness, and increase productivity. On the other hand, there is the risk that, in the event of some failure of an automated system, an inadequate cleaning process could go undetected for a period of time. When choosing a machine for automated cleaning, one should carefully consider the machine's capacity to monitor its effectiveness (e.g., temperature, chemical injection). Also, the instructions for using the machine should include sufficient information on how to prevent errors (e.g., how to attach connectors properly, how to load the devices to be cleaned) and a suggested maintenance program that will minimize failures that can lead to improper cleaning. Once the unit is operational, periodic verification of the automated cleaning process is also recommended to ensure that the cleaning process remains adequate.

5.3.2 Manual cleaning

Manual cleaning is a documented, validated, and reproducible procedure for effective device cleaning that involves a combination of hands-on wiping, brushing, and/or flushing with validated cleaning solutions and yields a device that is safe for use or ready for additional processing, as dictated by the device's intended use. Manual cleaning is performed when mechanical units are not available or instruments are too fragile or difficult to clean with a mechanical unit. Examples of devices that are commonly cleaned manually include microsurgical instruments, lensed or fiberoptic instruments, flexible endoscopes, and air-powered drills.

The essential elements of manual cleaning are hydration, friction, digestion, solubilization, and fluidics. By preventing drying, coagulation, or precipitation onto the device surface, hydration maintains the soil's water activity so that it is available for removal. Friction involves rubbing the soiled surface repeatedly, often with a tool such as a nylon brush, until the surface is visibly clean. Enzymatic digestion allows the breakdown of organic soil components to smaller, more soluble components, making them available for solubilization or suspension by detergents. Once the soil is soluble or suspended, it is more readily washed away by fluid motion.

It is generally recommended that immersible devices be cleaned under water to prevent aerosolization of microorganisms. For devices that cannot be immersed, it is important that manufacturers provide clear and comprehensive instructions on how to clean and rinse the devices without creating aerosols. Cool to lukewarm water–detergent solutions are recommended to prevent denaturation and thus facilitate the removal of proteinaceous substances. Instruments with small lumens or ports typically are cleaned with brushes and other cleaning accessories and then rinsed by irrigating cleaning fluids through their openings. The device manufacturer should provide any specialized attachments or equipment that will be needed or should direct the user to sources of such equipment. Examples of additional information that would be beneficial to the user include

a) the brush size required for cleaning lumened items;

b) the recommended method of drying (e.g., alcohol, soft cloths, pressured air); and

c) any quality testing and maintenance that might be required.

5.3.3 Mechanical cleaning

Mechanical cleaning is a documented, reproducible, automated or semiautomated (i.e., partially manual) cleaning procedure that is validated for use with medical devices and yields a device that is safe for use or ready for additional processing, as defined by its intended use.

Several mechanical cleaning methods are commonly used in health care facilities: ultrasonic cleaners, washer-sanitizers, washer-pasteurizers, washer-decontaminators, washer-disinfectors, and washer-sterilizers.

Currently, *ultrasonic cleaning equipment* provides the most effective means of removing soil from some medical devices. Ultrasonic cleaners use sound waves in a process called *cavitation* to disrupt the association of particulate matter with device surfaces. Cleaning is accomplished by means of high-frequency acoustic sound waves that are propagated through the aqueous medium in the water bath, creating microscopic bubbles. The bubbles attach to device surfaces and implode (burst inward), resulting in a vacuum action that pulls soil and debris off the items being cleaned. Low-level ultrasonic energy has little or no destructive effect on microorganisms and is therefore considered to be only a cleaning or sanitizing process, not a disinfecting or sterilizing process. Ultrasonic cleaners typically are used only after gross soil has been rinsed or wiped from the items to be cleaned. The water-detergent solution is changed before it becomes heavily soiled, because soil inhibits the cleaning action of the equipment. If the ultrasonic cleaner is not accompanied by a rinser-dryer or does not have a separate rinse cycle, it is necessary to rinse the items manually to remove the soil particles that are deposited on the items as the basket is being removed from the cleaning solution.

Ultrasonic cleaners are useful for cleaning devices that have joints or lumens that are difficult to reach manually (e.g., needles, stopcocks, and connectors). Because ultrasonic energy can loosen the fine screws of delicate instruments and destroy the glues or amalgam used in certain complex instruments, the device manufacturer should clearly warn the user if an ultrasonic cleaner will damage the device.

Washer-sanitizers of varying size and load capacity subject soiled items to wash-rinse cycles and a hot-water bath. This equipment generally operates at temperatures of 49 °C to 79 °C (120 °F to 175 °F) and requires 2 min to 10 min of contact time to reduce or destroy some types of microorganisms. Some models of washer-sanitizers provide a final rinse using a dilute concentration of a liquid chemical disinfectant.

NOTE—Dishwashers of the type used in hospital dietary departments are sometimes used for cleaning and sanitizing instruments and utensils. Tunnel washers are also sometimes used for this purpose. Cart washers are used to sanitize carts, mobile equipment, utensils, tote boxes, and various types of containers. Steam guns, which spray a water-detergent solution followed by a rinse, are also used for cleaning and sanitizing carts and other mobile equipment.

Washer-pasteurizers are commonly used to clean reusable anesthesia and respiratory tubings, masks, bags, and similar items. The system usually consists of two separate units, one for cleaning and one for disinfection. The cleaning unit rotates specially designed baskets in a clockwise motion to allow the detergent solution to flow in and around the items. The baskets of cleaned items are transferred manually to the second unit, where they are immersed in a water bath for at least 30 min at a temperature of 66 °C to 77 °C (150 °F to 170 °F). Some types of washer-pasteurizers provide a final bath in a cold chemical disinfectant solution (usually glutaraldehyde); items are immersed in this bath for the period of time necessary to achieve high-level disinfection. The items are then rinsed thoroughly to remove residues of the chemical disinfectant, which can be toxic.

Washer-decontaminators and *washer-disinfectors* are used to clean and thermally or chemically disinfect a wide assortment of medical devices. These systems create shear force from water velocity and dilution effects by using large amounts of water to disrupt soil from the medical device. Each of the several commercially available models cleans and washes to remove soil, but the method and level of disinfection vary from one manufacturer to another and one model to another. For example, some washer-decontaminators use an elevated temperature cycle (e.g., 93 °C (200 °F) for 10 min). Units that are specially designed to clean and disinfect flexible fiberoptic endoscopes and accessories are also available.

Washer-sterilizers clean medical devices by high shear forces and physical agitation developed with high-velocity steam or fluid sprays in a detergent solution. Following a rinse step, the devices are processed with a steam cycle. It is important to note that all applicable recommended practices of professional organizations include the precaution that devices to be subjected to the cleaning or sterilizing cycles of washer-sterilizers should first be rinsed with cold tap water and/or precleaned in ultrasonic cleaners to avoid cooking or baking debris onto device surfaces. Also, the steam cycle of a washer-sterilizer is not equivalent to a steam sterilization cycle, nor are items aseptically packaged; therefore, devices processed in a washer-sterilizer are considered safe for handling but not sterile.

The major advantage of automated equipment is that compliance with industrial or manufacturers' cleaning guidelines is increased. However, automated equipment is not available for or compatible with all medical devices that require reprocessing.

5.4 User verification of cleaning processes

5.4.1 General considerations

Verification of a cleaning process consists of

a) defining a cleaning process and its critical aspects so that each step is fully verifiable through personnel training and through observation to ensure that it can be followed completely, accurately, and without variation by all individuals who perform it; and

b) providing process controls along with validation and verification methodologies that ensure adequate, consistent cleaning levels.

Two principles are involved in the verification of the cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process on the basis of published and validated recommended practices or guidelines. The second concerns measuring and evaluating residual contaminants on medical devices after applying the established cleaning process.

The FDA places the primary responsibility for developing and validating methods for effective reprocessing of a reusable medical device on the manufacturer of the device. The manufacturer is expected to validate that the device can be cleaned and disinfected/sterilized adequately to allow the device to be reused. As outlined in FDA (1996), any labeling claims of fitness for reuse provided in the instructions for the handling, cleaning, disinfection, packaging, and sterilization of medical devices in a health care facility must be tested and validated by the manufacturer. To demonstrate compliance with label claims, manufacturers of cleaning agents must validate that their cleaners provide the expected level of soil removal and determine materials compatibility. (Other sections in this document address the issues related to manufacturers' validation testing for cleaning of medical devices.)

Medical device manufacturers should be familiar with cleaning, disinfection, and sterilization technologies used in health care facilities and the kinds of soil and microbial contamination encountered as a result of patient use. Organic soil such as blood, serum, lipids, tissue fragments, and inorganic salts can impede the disinfection or sterilization process if it is not removed during cleaning. Most of these soil components are substrates for the sterilants used for disinfection or sterilization; that is, they are competitors for sterilant action. If insufficiently cleaned, they can also hinder inactivation of microorganisms by limiting diffusion of the sterilant to the microorganisms' location on the medical device.

Users must then establish an appropriate cleaning protocol for the reusable medical devices used at their sites, using the recommendations of the device manufacturer and cleaner manufacturer, published data on cleaner efficacy for the medical devices (if available), and published and validated recommended practices or guidelines. Cleaning efficacy tests that are performed following reprocessing are used to verify the ability of a cleaning process to remove or reduce to an acceptable level the organic soil and microbial contamination that occurs during the use of reusable devices. A number of methods can be applied to evaluate the results of the cleaning process. The most common method is a visual inspection, sometimes involving the use of a lighted magnifying glass. Health care personnel inspect every device for visible organic soil and contamination in a simple functionality check, usually as part of the inspection, preparation, and packaging procedure. However, residual organic soil and microbial contamination might be present on an accessible surface, even though on visual inspection the device "looks clean." Furthermore, visual inspection is not possible for the inner components of medical devices that have lumens or are of nonsealed tubular

construction (e.g., flexible endoscope channels, laparoscopic accessory devices, biopsy forceps). Ideally, cleaning verification by users should include visual inspection combined with other verification methods that allow the assessment of both external surfaces and inner housings and channels of medical devices. Manufacturers should strive to provide users with such tests so that medical devices can be tested directly after cleaning in a fashion that will not damage the device or require recleaning.

A more objective and sensitive method than visual inspection is to measure the levels of organic soil and microbial contamination on the cleaned device. Currently, there are no validated test methods that allow users to rapidly verify that adequate cleaning has been performed. However, methods of measuring several soil components to determine the presence of nonvisible levels of organic soil and microbial contamination have been studied (see 7.4).

A critical aspect of in-use reprocessing is for users to verify that staff members who perform the reprocessing of medical devices using the protocol selected are consistently achieving the expected level of cleaning. Furthermore, part of an on-site quality assurance program should include ways to verify that the cleaning equipment used for reprocessing of medical devices is working properly. Zuhlsdorf, et al. (2002) have shown that in cleaning tubular devices the achievement of visible cleanliness and adequate microbial reduction varies greatly, depending on the type of water and detergent used for cleaning. The variability in cleaning achieved for lumens cleaned by automated washers (Zuhlsdorf, et al., 2002) underscores the importance of in-use verification for manual cleaning, which is generally less efficient than automated cleaning. In-use verification of staff competency and continued compliance with cleaning efficacy guidelines is rarely performed, primarily because of the lack of readily available methods of testing cleaning efficacy that are applicable to users. Many of the test methods available are research tools or are more appropriate for manufacturers to use to validate cleaning efficacy (e.g., destructive testing methods or sample methods involving the use of chemicals such as SDS to strip soil components from devices). Similarly, there are few methods for in-use verification that washer-disinfectors are working properly.

Two basic components of user verification of cleaning efficacy are

a) establishing reasonable benchmarks for the level of cleaning that can be achieved consistently for specific soil markers relevant to patient-used devices; and

b) developing rapid, easy-to-perform test methods that reliably demonstrate that the cleaning benchmarks have been achieved.

5.4.2 Markers

Cleaning is the removal of organic material (e.g., patient secretions), inorganic material (e.g., salts), and microbial contamination (acquired from the patient procedure or during handling) to ensure that adequate disinfection/sterilization can be achieved, thereby making the device safe for subsequent patient use. The few published studies that have evaluated the specific soil markers that can be used to determine cleaning efficacy have indicated that the following markers are useful for benchmarking purposes:

a) protein,

b) carbohydrate,

c) hemoglobin (blood),

d) endotoxin,

e) lipid,

f) sodium ion, and

g) bioburden.

Protein is the marker most commonly used for evaluating cleaning efficacy. Although viable count determinations are useful for manufacturers' validation studies, they should not be used as the sole marker for cleaning, because although any reprocessing method that results in loss of viability will show decreased levels of organisms, this decrease may not reflect actual "removal" but rather residual dead organisms that cannot be detected by viability assays. For in-use evaluation, viable counts are rarely used as markers for cleaning, because that method would require an incubation step that would make the evaluation far too time-consuming for users. However, for flexible endoscopes, where dry storage is critical, in-use samples of channels from stored scopes that are evaluated to determine the level of viable organisms can be used to determine whether microbial growth is occurring during storage.

What is not well established is the benchmark or acceptable residual level of markers that should be achieved by cleaning (see 7.5). Realistic benchmarks depend on what can be achieved by routine cleaning and the limit of

detection of the assay method used. Validation to establish benchmark levels for cleaning processes and residual soil has not yet been achieved. Recent data (Alfa, et al., 2002) indicates that after cleaning flexible endoscopes used on patients, the average levels of soil markers are as follows: protein, < 6.4 µg/cm^2; carbohydrate, < 1.8 µg/cm^2; hemoglobin, < 2.2 µg/cm^2; sodium ion, < 1 µmole/cm^2; and endotoxin, < 2.2 EU/cm^2 in the biopsy/suction channel. Furthermore, it has been reported that cleaning should be able to achieve at least a 3 $\log_{10}$ reduction in recoverable viable bacteria (total aerobic bacterial count) such that ≤ 4 $\log_{10}$ colony-forming units per square centimeter (cfu/cm^2) (corresponding to ≤ 10^5 cfu/device) remain inside the biopsy/suction channel after cleaning. For other medical devices such as laparoscopic assessory devices or surgical instruments that do not have lumens, the appropriate benchmarks may be different. Although there are few published studies to validate soil cleaning benchmarks for surgical instruments, Kruger (1997) has suggested that > 20 µg/cm^2 of protein remaining on surgical instruments is unacceptable; however, the rationale for this benchmark is not given. Chan-Myers, et al. (1997) have shown that for rigid, lumened medical devices after cleaning, there is ≤ 10^3 cfu/device. The benchmarks for residual soil and bioburden level after cleaning may become more definitive as more data becomes available and/or more efficient cleaning methods are developed.

5.4.3 Cleaning verification tests for users

Although assay methods exist for all of the markers described in 5.4.2, there are few commercially available tests that can be adapted to verify in-use cleaning compliance. Many existing test methods have not yet been validated to demonstrate that they can achieve the postcleaning levels that have been published. Tables 3 and 4 summarize the currently available test methods that apply to in-use evaluation of, respectively, efficacy of cleaning of medical devices and efficacy of washer-disinfectors used for medical device reprocessing. Few of the in-use test methods listed in the tables have been assessed to determine their correlation with the postcleaning levels indicated above.

Ideally, cleaning tests for in-use verification of medical device reprocessing should be

a) rapid,

b) easy to perform,

c) sensitive (i.e., meet realistic benchmarks),

d) accurate,

e) repeatable,

f) free of interfering substances, and

g) robust (i.e., not requiring exacting conditions or time constraints that cannot be achieved in routine reprocessing areas).

Again, manufacturers should strive to provide users with rapid cleaning verification tests so that medical devices can be tested directly after cleaning in a fashion that will not damage the device or require recleaning. It is important to note that eluting samples from used medical devices using an SDS solution requires that the device be recleaned after testing. Consequently, although this sampling method is useful for research purposes because it facilitates sample collection, it has little value for in-use testing because the medical device would need to be recleaned to remove any residual SDS. Moreover, easy-to-perform tests are needed that will verify the functionality of automated washers. Such tests should not lead to the introduction of interfering or extraneous materials that may remain on medical devices after testing.

For verification of routine cleaning processes, users should strive to incorporate a test method that verifies the functionality of the automated washer (if used) as well as a test method that verifies the cleanliness of specific devices after manual and/or automated cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with expected cleaning benchmarks (once these benchmarks have been defined).

Table 3—In-use tests available to assess efficacy of cleaning of medical devices*

Test method	Soil component tested	Limit of detection	Limitations	Length of test (after sample collection)
OPA (o-phthaldialdehyde) method (Fengler, et al., 2001; Verjat, et al., 1999). Swab device or elute device with liquid, then test sample using OPA method.	Protein	0.01 µg/mL	Sensitivity unrealistic (i.e., routine handling with hands could trigger positive reaction).	≈ 1 min to 5 min
Biuret reaction (Kruger, 1997). Swab device, immerse in reagent, and assess for color development.	Protein	5.5 µg/cm^2	Not applicable to lumens. Kruger (1997) suggests that > 20 µg/cm^2 is unacceptably high for protein, but no rationale is given for this benchmark. Rust causes color interference.	10 min
Protein method. Swab device, immerse in reagent, and assess for color development.	Protein	Not indicated	Not applicable to lumens. No indication of what level of soiling produces positive test result.	Stated as "minutes"
ATP (adenosine triphosphate) method. Swab device, extract ATP from swab, determine ATP, or use fluid rinse as sample.	ATP (present in eukaryotic cells and live bacteria)	Not indicated	Instrumentation to read test. Requires cells (eukaryotic or prokayotic) to be present. No ATP is detected if only protein or carbohydrate is present.	30 s
ATP bioluminescence (Davidson, et al., 1999).	Bacteria (*S. aureus* and *E. coli*)	< 10^4 cfu/ 100 cm^2	Not indicated.	Minutes
Ninhydrin test (de Bruijn, et al., 2001). Swab device, immerse swab in test reagent, and assess for color development.	Protein	2.5 µg/ swab	Not applicable to lumens; interference in color detection by rust, etc., from cleaned devices that mask swab color.	20 min
UV-VIS spectroscopy (Knieler, 2001).	Residual blood	Not indicated	Not indicated.	Not indicated
Limulus amoebocyte lysate assay (LAL). Elute device with liquid, then test sample using LAL method.	Endotoxin	0.0032 EU/mL	Sensitivity unrealistic (i.e., routine handling could trigger positive reaction); does not detect proteins, organic matter, or viable microorganisms.	10 min to 30 min

* More comprehensive lists of test soils and test methods are provided in Tables 5 and 6.

Table 4—In-use tests available to assess efficacy of washer-disinfectors used for medical device reprocessing*

Test method	Soil component tested	Limit of detection	Limitations	Length of test (after machine protocol is finished)
Visual test soil. Colored paste painted onto medical device. After cleaning, visual inspection of device to confirm removal of soil.	Artificial soil (not linked to specific soil components); detected as color being present or absent.	Not indicated	Introduction of foreign material to medical devices that will subsequently be used on patients after cleaning.	≈ 1 min
Coagulated blood test. Metal coupon with strip of coagulated blood soil. After cleaning, visual inspection with comparison to chart to confirm removal of soil. A lumen version is available for testing lumen washers.	Blood and protein; detected as visible red (blood) or visible "film" (fibrin, protein).	Not indicated	Valuable as a QA indicator for functionality of washer-disinfector but NOT an indication of cleaning verification for specific medical devices in the washer.	≈ 1 min

* More comprehensive lists of test soils and test methods are provided in Tables 5 and 6.

5.5 Cleaning tools and accessories

Cleaning tools and accessories are an overlooked but vital component of a validated cleaning process. Cleaning tools and accessories can be either reusable or disposable products.

In the case of reusable cleaning tools such as scrubbing pads, wiping cloths, connectors, and long bottle brushes, there is always the risk of cross-contamination from one medical device to the next. A validated cleaning process using any reusable components will have to include the cleaning process for these components themselves, which can considerably increase the complexity (and thus the chance of failure) of the overall cleaning process. In addition, the issue of wear must be considered for reusable tools such as brushes, particularly when they are used to scrub the channels of long and narrow lumens. As the bristles wear from constant use, the efficacy of these tools can be greatly reduced, so the tools will need to be inspected and replaced on a regular basis.

In the case of disposable cleaning tools, the issue of cross-contamination is eliminated, as is the need for a cleaning process for the tools themselves. The additional cost of disposable tools has to be balanced against the cost of cleaning, inspecting, and occasionally replacing reusable tools.

Accessories can be parts of an automated cleaning process; examples include brushes and the soft polymer tubing attachments designed to collect and channel water through medical devices. Such accessories should be inspected for wear and replaced on a regular basis. The softer, thinner, and more pliable a piece of plastic, the more vulnerable it will be to aging in the extreme environment of an automated washer. These plastic accessories should also be inspected regularly to detect particles that may have become lodged within them and ensure that they have not become twisted, kinked, or flattened so as to prevent the flow of cleaning agents through them.

5.6 Worker education

Worker education is the responsibility of health care facilities and is supported by the manufacturer through the provision of clear, specific, comprehensive instructions that can be understood by health care personnel responsible for cleaning the device.

Manufacturers can be of particular assistance to health care facilities by

a) providing in-service education (ideally, a personal demonstration by a representative of the manufacturer and return demonstrations, if possible); and

b) providing training videos, which allow flexibility in scheduling and are especially helpful in training new employees and making annual updates.

6 Test soils

6.1 Overview

After a medical device has been used on a patient, it must be cleaned and disinfected/sterilized to ensure that it does not pose a risk of transmitting infectious microorganisms to the next patient. Cleaning medical devices involves the physical removal of organic material and microorganisms after a device has been used in a patient procedure. The objective is to remove as much of the organic load and bioburden as possible, thereby ensuring that the device does not present an unreasonable challenge to the terminal disinfection or sterilization method used. It has been well established that the presence of residual foreign soil (such as organic and inorganic materials, microorganisms, and lubricants) on a device reduces the effectiveness of disinfection and/or sterilization of the device (AAMI TIR12; Chartier, et al., 2001; Chu and Favero, 2000; Miles, 1991; Rutala and Weber, 1999a; Rutala and Weber, 1999b). There is ample evidence in the literature that improperly reprocessed medical devices can lead to transmission of infectious disease (Agerton, et al., 1997; Alvarado and Reichelderfer, 2000; ANSI/AAMI ST35; CDC, 1999; Cowen, 2001; Deva, et al., 1998; Feigel and Hughes, 1999; Michele, et al., 1997).

Because devices vary in size, complexity of design, fragility of materials, and sensitivity to cleaning solutions and methods, it is necessary for manufacturers of reusable devices to provide validated cleaning protocols for safe and effective reprocessing in the form of complete and comprehensive written instructions for cleaning their products. In addition, there is a need for manufacturers of washer-disinfectors and other automated cleaning equipment to demonstrate the efficacy of their processes on various reusable medical devices. To this end, the FDA, ASTM International, and AAMI recommend that “simulated-use” testing should include a representative inorganic and organic challenge that mimics actual in-use conditions (AAMI TIR12; ASTM International, 2003; FDA, 1996, 2000a, 2002). Furthermore, the guidelines recommend that the organic challenge should be “representative of the types of soil to which devices are exposed during clinical use, such as serum blood, secretions, etc.” (AAMI TIR12).

Over the years, various artificial test soils have been developed for simulated-use cleaning in the laboratory. These test soils include Hucker’s soil, Edinburgh soil, British Standard soil, artificial test soil (ATS), radionuclide-labeled blood, serum, and various combinations of whole blood, fibrin, mixtures of serum, dry milk powder, blood, and saline (AAMI TIR12; FDA, 1996, 2000a, 2002; Jacobs, 1998; Society of Gastroenterology Nurses and Associates, 1999). Because of the wide range of soils used, it has often been difficult to compare the data obtained. As pointed out by Jacobs (1998), Hucker’s soil, Edinburgh soil, Koller soil, Birmingham soil, and British Standard soil were designed primarily to present cleaning challenges for assessing the efficacy of washer-disinfectors for anesthetic equipment and bedpans. The formulations used in these soils were based on common sense rather than scientific data. Recent analysis indicates that these soils represent a challenge that is beyond the worst-case levels seen in uncleaned devices used in patients (Alfa, et al., 1999). Recent data suggests that other markers such as carbohydrate, hemoglobin, and endotoxin are also important considerations in assessing cleaning efficacy (Alfa, et al., 1999; Alfa, 2001). In addition to an organic challenge, the presence of bioburden is also an important consideration, because various organisms adhere differently to different surface polymers. Cleaning data from narrow-lumen sphincterotomes has demonstrated that, despite adequate removal of protein, carbohydrate, and hemoglobin, residual organisms remain (Alfa, 2001). This data indicates that resistance to removal by cleaning is more pronounced for vegetative bacteria than for spores. This supports the value of using vegetative microbial challenges and not relying solely on spores as cleaning markers.

Ideally, the ingredients of artificial test soils should be representative of the challenges expected in use for the device being evaluated. They should also be easy to obtain from commercial sources and easy to blend in a laboratory using readily available supplies and equipment, and should meet OSHA regulations for occupational exposure to bloodborne pathogens (29 CFR 1910.1030). The drying time for the soil on the device should mimic what might occur in use. Surrogate carriers might be useful, but some testing of the actual medical device should also be undertaken using simulated-use and/or clinical in-use tests.

The following sections discuss considerations in the choice of a test soil and describe many of the artificial test soils that have been used. Visual inspection of the cleaned device is often used as the clinical endpoint of “clean.” However, visual inspection cannot detect the presence of microorganisms, endotoxin, cleaning chemical residue, or patient blood and tissue in long, narrow, opaque lumens. Thus, visual inspection might not be adequate for simulated-use testing in the laboratory. Consequently, in addition to qualitative inspection, quantitative methods are needed to detect the presence of residual artificial test soils after cleaning inside and outside of devices. Lastly, one must determine the residual level that is allowable for a device to be considered “clean.”

6.2 Scientific data for choice of test soil

No one test soil is necessarily appropriate for all medical device testing. The worst-case organic and bioburden challenge that is realistic for devices that enter sterile body cavities is quite different than that for devices that contact mucosal surfaces. Kruger (1997) indicated that “the general viewpoint prevails that protein-containing residues present the prime challenge for medical devices and must be removed by cleaning. Accordingly the test soils should be protein based.” Although there is no doubt that protein is a major soil component in medical devices used on

patients, the benchmark data from flexible endoscopes and the data from patient-ready endoscopic retrograde cholangiopancreatography (ERCP) scopes from a recent trans-Canada survey (Alfa, et al., 2002) suggest that carbohydrate and, to a lesser extent, hemoglobin and endotoxin are also common soil parameters found in patient-ready flexible endoscopes. Those findings support the value of using a test soil that allows quantitative detection of a variety of soil components, not just protein. Indeed, data for simulated-use testing demonstrated that for flexible endoscopes that have been suboptimally cleaned, hemoglobin, carbohydrate, and endotoxin are all more likely than protein to remain in higher levels relative to levels detected after total cleaning (Alfa, et al., 2002).

For intravascular devices and devices used for surgical procedures in sterile body cavities, whole blood or a dilution of blood or serum would be appropriate. The worst-case soil levels would be the protein, carbohydrate, and hemoglobin ranges expected in whole blood. (Endotoxin should not be present unless acquired through handling after the procedure.) The bioburden challenge has been shown to be low (73 % ≤ 100 cfu/device) in such devices, with the worst-case level being 10^4 cfu/device (Chu, et al., 1998). The microorganisms represent those acquired during handling and washing, as the surgical site would be sterile. Soils that reflect these worst-case ranges and contain a bioburden of approximately 10^4 cfu/device would be appropriate for cleaning validation studies of medical devices used in this context.

Mucosal surfaces are very different from sterile body sites, in that the organic challenge is different (both in concentration and composition) and the microbial load is substantial. The substantial microbial load includes high concentrations of Gram-negative organisms, so the presence of endotoxin is a consideration in assessing cleaning efficacy. Although endotoxin is a major concern for medical devices used in sterile body sites, this component would not be expected to be present in large amounts during normal reprocessing of such devices. Data from samples taken from flexible endoscopes that contact the mucosal surfaces of the gastrointestinal tract or lungs had worst-case levels of protein of 2200 μg/mL; carbohydrate, 559 μg/mL; hemoglobin, 670 μg/mL; endotoxin, 189,188 EU/mL; and viable bacteria, 10^8 cfu/mL (Alfa, et al., 1999). The ATS soil described by Alfa and Jackson (2001) and Alfa (2001) has been shown to allow assessment of all of these soil components. Data from many studies has confirmed that the bioburden challenge on exposure to mucosal surfaces can be very high: a median of approximately 10^6 cfu/device and a worst case of 10^{10} cfu/device (Alfa, et al., 1999; Chu, et al., 1998).

6.3 Test soils and methods for washer-disinfectors

Several countries have developed test soils to test the efficacy of cleaning various types of medical devices in washer-disinfectors. Table 5 lists national test soils that may be used to demonstrate the efficacy of cleaning for the various load types in washer-disinfectors. These test soils consist of formulations ranging from citrated cattle blood coagulated with calcium chloride to complex combinations of such ingredients as egg yolk, hog mucin, flour, semolina pudding, water-soluble adhesive wallpaper paste, *Pseudomonas* species biofilm, and bovine fibrinogen. The test soils listed in Table 5 are not necessarily of equivalent sensitivity in demonstrating cleaning efficacy.

Table 5—Test soils for washer-disinfectors

Country	Reference	Constituents of soil	Load type
Austria	Koller (1981)	Nigrosin, oatmeal, egg, dehydrated potato flakes, water	Surgical instruments (including rigid endoscopes)
Germany	Bundesgesundheitsblatt (1980)	Blood, egg yolk, semolina pudding	Surgical instruments (including rigid endoscopes)
Netherlands	Orzechowski and de Bruijn	Bovine albumin fraction 5, porcine gastric mucin type 3, bovine fibrinogen fraction 1	Surgical instruments (including rigid endoscopes)
Sweden	SPRI (1988)	Citrated cattle blood coagulated with calcium chloride	Surgical instruments (including rigid endoscopes)
United Kingdom	BSI (1993b) U.K. Dept. of Health (2001)	Defibrinated horse blood, egg yolk, dehydrated hog mucin	Surgical instruments (including rigid endoscopes)
Sweden	SPRI (1988)	Citrated cattle blood coagulated with calcium chloride	Hollow ware
United Kingdom	BSI (1993b)	Defibrinated horse blood, egg yolk, dehydrated hog mucin	Hollow ware
Germany	Bundesgesundheitsblatt (1980)	Blood, egg yolk, semolina pudding	Anesthetic accessories

Table 5 *(continued)*

Country	Reference	Constituents of soil	Load type
Sweden	SPRI (1988)	Citrated cattle blood coagulated with calcium chloride	Anesthetic accessories
United Kingdom	BSI (1993b)	Glycerol, dehydrated hog mucin, horse serum, unbleached plain flour, aqueous safranine solution, water	Anesthetic accessories
Germany	Bundesgesundheitsblatt (1980)	Blood, egg yolk, semolina pudding	Glassware for infants
Sweden	SPRI (1988)	Citrated cattle blood coagulated with calcium chloride	Glassware
United Kingdom	BSI (1993b)	Defibrinated horse blood, egg yolk, dehydrated hog mucin	Glassware
Austria	Koller (1981)	Nigrosin, oatmeal, egg, dehydrated potato flakes, water	Bedpans
Germany	DIN (1994)	Bovine albumin, mucin, maize starch	Bedpans
Sweden	SPRI (1988)	Citrated cattle blood coagulated with calcium chloride	Bedpans
United Kingdom	BSI (1993a)	Unbleached plain flour, water-soluble adhesive wallpaper paste, hen's egg, black India ink, water	Bedpans
Sweden	SPRI (1988)	Citrated cattle blood coagulated with calcium chloride	Bedpans
United Kingdom	BSI (1993a)	Defibrinated horse blood, water-soluble adhesive wallpaper paste, black India ink	Bedpans
Sweden	SPRI (1988)	Citrated cattle blood coagulated with calcium chloride	Urine bottles
United Kingdom	BSI (1993a)	Defibrinated horse blood, water-soluble adhesive wallpaper paste, black India ink	Urine bottles
France	Pineau, et al. (1997)	Biofilm formed by *Pseudomonas* spp.	Flexible endoscopes
Germany	Kramer (1995)	Blood	Flexible endoscopes
United Kingdom	U.K. Department of Health (2001)	Glycerol, dehydrated hog mucin, horse serum, unbleached plain flour, aqueous safranine solution, water	Flexible endoscopes
Germany	Zuhlsdorf, et al. (2002)	*E. faecium*, protamine, heparinized blood	Flexible endoscopes
Netherlands	Orzechowski and de Bruijn	Bovine albumin fraction 5, porcine gastric mucin type 3, bovine fibrinogen fraction 1	Stainless steel items
Sweden	SPRI (1988)	Calcium stearate generated *in situ* from soap and calcium chloride solution	Wash bowls

6.4 Other test soils and methods for reusable devices

Other test soils have been proposed for use in demonstrating the efficacy of cleaning for various types of devices or simulated devices and materials. Table 6 lists some of these artificial soils and the devices that were tested.

Table 6—Test soils for reusable devices

Author(s)	Constituents of soil	Device
AAMI TIR12 (Hucker's)	Peanut butter, evaporated milk, butter, flour, lard, dehydrated egg yolk, saline, printer's ink, blood	Not specified
Alfa and Jackson (2001)	ATS-B (bacteria, protein, carbohydrate, endotoxin, hemoglobin)	Flexible colonoscope
Anderton and Nwoguh (1991)	*Klebsiella aerogenes*	Enteral feeding tubes
Bar, et al. (2001)	*Mycobacterium tuberculosis*	Bronchoscope
Chartier, et al. (2001)	Yeast extract, native human albumin, defibrinated native sheep blood, bovine serum, fibrin, Tween 80, water	Microplates
Donlan, et al. (2001)	*B. stearothermophilus* spores, *E. cloacae* biofilm	Needleless connectors to central venous catheters
Green, et al. (2001)	Oils, calf serum, albumin, gelatin, hog mucin, egg white	Microplates
Kozarek, et al. (2001)	*B. stearothermophilus* spores	Double-channel sphincterotomes
Merritt, et al. (2000a)	Bacteria, mammalian cells, albumin, bovine fibrin, bovine fibrogen	Microplates
Mostafa and Chackett (1976)	Radiolabeled human serum albumin	Surgical instruments
Orzechowski, et al. (2000)	Bovine albumin, mucin, fibrogen	Dental handpieces
Penna and Ferraz (2000)	*B. subtilis* in radioopaque iodine contrast, bovine blood with EDTA	Angiographic catheters, spinal needles
Pfeifer (1998a, 1998b)	Albumin, hemoglobin, fibrinogen, thrombin	Surgical instruments
Roth, et al. (1999b)	a) Radioactive marked macroalbumins b) *S. aureus*, *P. aeruginosa*, heparinized sheep blood, protamine	Biopsy forceps, papillotome, Dormia basket
Rowan and Anderson (1998)	*Bacillus cereus*	Infant feeding bottles
Schrimm, et al. (1994)	Radiolabeled marker macroalbumins	Tubular instruments
Verjat, et al. (1999)	Human albumin solution	Hemolysis glass tubes, surgical steel blades, ceramic penicylinders
Working group (1995)	Microorganisms in oleic acid-albumin-dextrose-catalase	Endoscopes

7 Test methods, equipment, and acceptance criteria

7.1 Overview

In devising test methods for the validation of cleaning procedures, the technique for and site(s) of application of test soils are important considerations. In particular, the location of the soil, method of inoculation, and length of time allowed for the soil to dry on the device are important, but not extensively studied, aspects of cleaning protocols.

These study parameters should be well documented to facilitate comparison of the various soils, surrogates, and protocols. The experimental design should allow for positive controls (soiled but not cleaned) and negative controls (not soiled or cleaned), as well as the experimental samples (soiled and cleaned). This section of the TIR covers soil application, test carriers, cleaning test methods, detection methods for residual test soil on devices, and cleaning acceptance criteria.

7.2 Soil application

Because the time that a medical device sits between use and the commencement of cleaning varies, test conditions should include both liquid and dried-on soil. Such conditions help define the efficacy boundaries of cleaning. The drying times should include a realistic minimum and an extended reprocessing transit time (e.g., overnight at room temperature) that reflect in-use conditions for the device. For some devices, the method of inoculation has been chosen to represent the manipulations expected during use of the device on the patient (Roth, et al., 1999a). Alternatively, part or all of the medical device or surrogate carrier may be inoculated with the soil or bioburden challenge. Either method of inoculation is acceptable, provided that adequate controls are included to demonstrate that soiling results in reproducible levels of recoverable soil and organisms.

7.3 Test carriers

7.3.1 Surrogate carriers

Appropriate surrogate carriers readily allow for destructive and *in situ* testing and should be composed of materials and have dimension constraints that reflect the test device being evaluated. For example, if the device contains narrow lumens, using a surrogate carrier composed of tubing that has similar material composition and dimensions would be appropriate. Such surrogate carriers may be simple coupons, lengths of tubing, or more sophisticated surrogates such as those composed of multiple tubes and connectors used to mimic the complexity of the test device (Tatalick, 1996). Testing with surrogate carriers is sometimes the only way to allow direct evaluation of residual soil (i.e., by destructive testing or *in situ* test methods). The Bradford's test for protein, an *in situ* method described by Merritt, et al. (2000a), is an excellent way to detect protein residuals; however, interfering substances or materials may prevent it from being used directly in a medical device. In such cases, surrogate carriers may be the more cost-effective way to facilitate such test methods.

7.3.2 Medical devices

Simulated-use testing using the actual medical device is the best way to validate cleaning methods. However, to obtain the number of replicate tests, indirect sample methods might be necessary, depending on the design of the medical device. Samples should be tested for each stage of the cleaning validation protocol and should include both negative and positive controls. The number of replicates should be sufficient to ensure statistical validity. Depending on the statistical variation in test results, it might be necessary to adjust the number of samples.

7.4 Assays of residual soil and bioburden

7.4.1 General considerations

Many options are available to visualize or quantify the amount of residual test soil remaining on cleaned devices. Scanning electron microscopy has been used to detect the presence of biofilm and debris on device surfaces (Society of Gastroenterology Nurses and Associates, 1999), and the use of a dissecting microscope to look for debris on surgical instruments has also been suggested (Buettner, 1995). Depending on the composition of the test soil used for simulated-use studies, one can measure the presence of bacteria, protein, lipids, carbohydrate, hemoglobin, or endotoxin. Many of the detection methods for given test soils are provided in the references cited in section 6.

7.4.2 Destructive methods

Destructive testing involves cutting up the medical device and immersing the pieces in a defined volume of sterile water (either reverse-osmosis-treated or distilled water). Thorough perfusion of all lumens, sonication, and mixing should be performed to ensure adequate removal of residual soil. This method ensures that all surfaces (including internal surfaces) are eluted into the sample for testing. In addition, 1 % (w/v) SDS can be used in conjunction with sonication and mixing to ensure efficient elution (Fengler, et al., 2000a, 2000b, 2001). The eluate obtained may then be assayed using traditional protein (dye-binding Coomassie blue or OPA method) (Verjat, et al., 1999), carbohydrate (Liu, et al., 1994), hemoglobin (e.g., commercially available 3,3',5,5'-tetramethylbenzidine (TMB) method), and endotoxin (using the LAL (Limulus Amoebocyte Lysate) method) assays. Appropriate controls are needed to demonstrate that SDS, if used, does not interfere with the assay method used. SDS should not be used when samples will be assayed for viable counts, as this detergent at 1 % (w/v) will significantly reduce the viability of a range of microorganisms.

7.4.3 Tracer methods

Radionuclide tracers and ATP have both been used to monitor cleaning efficacy. The radionuclide method is very sensitive and provides excellent ability to monitor removal of the soil that has been tagged with a radioactive tracer (Roth, et al., 1999a). However, it is not widely available and requires special equipment, permits, and training because it uses radioactivity. Rapid ATP assays have frequently been used in the food and beverage industry to monitor surface cleanliness. Recently, ATP bioluminescent methods have been suggested as a means of monitoring the cleanliness of medical devices; however, the ATP levels detected were not calibrated to indicate the level of soiling that they represented (Takashina, 2001). Furthermore, since ATP is found only in viable organisms and eukaryotic cells, it would not necessarily be appropriate for use in monitoring the cleaning of medical devices soiled with a test soil, such as serum, that lacks these components (i.e., no bacteria and no blood cells).

7.4.4 In-situ methods

The value of using a direct *in situ* test method for protein has been demonstrated by Merritt, et al. (2000a). The use of Bradford's reagent is an excellent way to determine whether protein residuals remain after cleaning. It is particularly well suited for testing lumens and was used by Alfa (2001) to demonstrate that in single-use triple-lumen sphinctertomes, the cautery wire channel was not being cleaned properly during reprocessing. The test is simple; the medical device is immersed in undiluted Bradford's reagent or the channel is filled with reagent. The reagent is allowed to remain in contact with the device for 10 min to 20 min at room temperature. If there is residual protein, the Bradford's reagent will turn blue. This color reaction can be detected visually or determined quantitatively using a spectrophotometer at 595 nanometers (nm). If the device contains no residual protein (or levels less than the limit of detection for the Bradford's reagent), the reagent will remain colorless.

Other direct test methods that have been described use surface chemistry analysis (Tucker, et al., 1996) and photoelectron spectroscopy (Reichl, et al., 1995). Although these methods are very useful, the availability of the specialized equipment for surface chemistry analysis is limited.

7.4.5 Indirect sample elution

If destructive or *in situ* testing is not possible, then fluid (with or without 1 % SDS) can be used to elute a sample from the intact device, either by immersing the device in fluid containing 1 % SDS or by flushing (or aspirating) the elution fluid down the channels of the device (Fengler et al., 2000c, 2000d, 2001). The sample eluted can then be tested to determine residual soil or bioburden levels. Where possible, *in situ* or destructive testing is preferred to indirect sample elution.

7.4.6 Viable bioburden assessments

Samples obtained by either destructive methods or indirect elution should be quantitatively assessed using standard filtration, pour-plate, or spread-plate methods. Neutralization of detergent or disinfectant residuals (where applicable) might be necessary for pour-plate and spread-plate methods, but it is unnecessary for filtration. A generally acceptable nonspecific neutralization method includes the addition of 10 % serum to the sample after elution. Other more specific neutralization additives can be used, as applicable. The choice of culture medium depends on the test organism (blood agar, Tryptic soy agar, or any other microbiologically supported medium is acceptable). For cleaning validation, a representative Gram-negative bacterium (e.g., *Pseudomonas aeruginosa*, *Escherichia coli*, *Acinetobacter* spp.) and a representative Gram-positive bacterium (e.g., *Enterococcus faecalis*, *Staphylococcus aureus*) should be included. Spores can be used as marker organisms, but, because they are metabolically inactive, their adherence characteristics are not the same as those of vegetative organisms. The bacteria and spores are used for assessment of the bioburden reduction as a result of cleaning. They are not a substitute for soil markers for cleaning efficacy. It is possible that if the cleaning reagents kill the test organisms, the organisms may still adhere to the device, and debris (e.g., protein, endotoxin) could still remain on the device. It is difficult to differentiate a reduction in bacterial numbers as a result of killing from a reduction because of physical removal. Therefore, both soil and bioburden markers are needed for cleaning validation.

7.4.7 Specific tests for protein, lipids and oil, carbohydrate, and endotoxin

7.4.7.1 Protein

The presence of residual protein can be visually or quantitatively assessed by one or more of the following test methods:

a) protein staining with ninhydrin stain (Chartier, et al., 2001; Kiel, 1993);

b) Biuret reaction (Kruger, 1997; Fengler, et al., 2001);

c) microbiocinchoninic acid test kit (Orzechowski, et al., 2000), Bio-Rad protein assay (Alfa, et al., 1999), Bradford reagent (Green, et al., 2001);

d) Naphthol Blue Black, Brilliant Blue R, and Bradford Reagent (Merritt, et al., 2000a);

e) a modified OPA method (Fengler, et al., 2000b, 2001; Michels, et al., 1996);

f) chemical analysis (Working Group, 1995);

g) the folin phenol method (Tripathi and Tripathi, 1992); and

h) measuring the radioactivity of radiolabeled protein tracers (Roth, et al., 1999a, 1999b; Mostafa and Chackett, 1976).

Although not applied to determine protein residuals on devices, other methods of detecting protein residuals include assessment of fluorescence quenching of erythrosin B (Ma, et al., 1996) and the Rayleigh light scattering technique with acid green 25 (Ma, et al., 1997).

Although not specifically directed at detecting protein, the method of ATP bioluminescence can detect ATP derived from residual viable organisms or eukaryotic cells (Griffith, et al., 2000). This method has been applied to monitor surface cleaning in the food industry for many years.

7.4.7.2 Lipids and oils

The presence of residual lipids and oils on reusable medical devices can be visualized by several methods, including the use of Nile Red dye (Mirejovsky, et al., 1991). Cottonseed oil can be detected by Oil Red O, Fat Red, Sudan IV, and Sudan Black B (Merritt, et al., 2000b). The presence of residual cottonseed oil, mineral oil, glycerin, and silicone oil on microtiter plates was measured at 215 nm and 220 nm in a plate reader.

7.4.7.3 Carbohydrates

Carbohydrates are a significant constituent of biofilm. Liu, et al. (1994) described a technique to estimate biofilm accumulation on glass plates by measuring carbohydrate in biofilm scraped from the plates. However, such a method will not detect the presence of dead microorganisms and debris that could still adhere to device surfaces. The artificial test soil of Alfa and Jackson (2001) contains carbohydrate and has been used to monitor cleaning of medical devices using the phenol-sulfuric acid method described by Liu, et al. (1994).

7.4.7.4 Endotoxin

Endotoxin can cause pyrogenic reactions and is particularly problematic if left on reusable medical devices that are considered “critical” and enter sterile body cavities. Endotoxin is a constituent of the cell wall of Gram-negative bacteria, and reusable medical devices can be exposed to Gram-negative bacteria during use (if in contact with mucosal surfaces) or reprocessing (tap water often contains Gram-negative bacteria). The significance of residual endotoxin on semicritical devices (e.g., flexible endoscopes) is not known. Alfa and Jackson (2001) included endotoxin in their artificial test soil. Endotoxin levels eluted from cleaned medical devices can be measured by various methods (ANSI/AAMI ST72).

7.4.7.5 Hemoglobin

Blood cells contain hemoglobin, and adequate cleaning should remove it. Methods of testing for residual hemoglobin in samples eluted from medical devices include a hemoglobin strip test (Fengler, et al., 2001) and standard quantitative hemoglobin assays (Alfa, et al., 1999).

7.5 Acceptance criteria

One of the most difficult issues to address is “how clean is clean enough.” Several investigators have suggested acceptance criteria for residual protein (Alfa, et al., 1999; Kruger, 1997; Fengler, et al., 2000b; Michels, et al., 1996;

Fengler, et al., 2001; de Bruijn, et al., 2001; Alfa, et al., 2002). Fewer opinions have been published regarding other soil components (Alfa, et al., 2002).

Some data is available for protein levels before and after cleaning. The OPA method has been used to assess the removal of proteins from stainless steel surgical devices, and "clean" benchmarks of 0.01 μg/device and 0.1 μg/device have been proposed by Fengler, et al. (2000b, 2001) and Verjat, et al. (1999), respectively. However, using the 0.01 μg/device benchmark, Fengler, et al. (2000b, 2001) found that almost half of all of the laparoscopic devices tested were positive for residual protein. Even a fingerprint on the assay tube could cause a false-positive reaction with the OPA method. Given how surgical devices are handled during reprocessing, the benchmarks of 0.01 μg/device and 0.1 μg/device appear to be unrealistic.

The ninhydrin test has also been proposed and evaluated as a rapid cleaning validation test for users (de Bruijn, et al., 2001). This is also a test for protein, but it is much less sensitive (5 $\mu g/cm^2$ area tested) than the OPA test. The ninhydrin test was reported as problematic because in-use testing showed that after cleaning there was too much interference with the ninhydrin color detection from rust or other colored debris on the cleaned surgical instruments that were tested. Other data has also suggested that for stainless steel surgical devices, a protein level of < 5 $\mu g/cm^2$ is a reasonable cleaning benchmark (Kruger, 1997). This protein benchmark is several magnitudes greater than that suggested for the OPA method. The benchmarks for easily cleaned stainless steel surgical devices will no doubt differ from those for devices such as flexible endoscopes, which are more difficult to clean. Published data for flexible endoscopes has shown that residual protein of up to 320 μg/device (with a median of 6.4 $\mu g/cm^2$) remains, despite very thorough manual cleaning of a flexible colonoscope using currently accepted guidelines (Alfa, et al., 1999; Alfa, et al., 2002). There is little value in setting a cleaning cutoff that is beyond the capacity of the available in-use manual cleaning methods. Currently, the limited published data (Alfa, et al., 2002) for flexible endoscopes indicates that the average levels of markers after cleaning are as follows: protein, < 6.4 $\mu g/cm^2$; carbohydrate, < 1.8 $\mu g/cm^2$; hemoglobin, < 2.2 $\mu g/cm^2$; and endotoxin, < 2.2 EU/cm^2. These benchmarks might become more definitive when more data and more efficient cleaning methods become available, but they are a reasonable starting point at present. For all cleaning benchmarks, the data should be presented as $\mu g/cm^2$ to allow comparison of different devices.

For bioburden reduction by cleaning, the published data indicates that it should be possible to show at least a 3-$\log_{10}$ reduction in viable counts after manual cleaning of flexible endoscopes (Alfa, et al., 1999; Chu, et al., 1998). Zuhlsdorf, et al. (2002) have shown that for some automated cleaning processes for flexible endoscopes, 4-$\log_{10}$ reductions in viable counts are *not* achievable. Furthermore, for rigid lumen devices and surgical instruments, the bioburden levels after patient use but before cleaning are low (< 1,000 cfu/device), and these levels of bioburden are replaced by low levels of water organisms during the cleaning process (Chan-Myers, et al., 1997; Chu, et al., 1998). This data indicates that a bioburden reduction from cleaning of at least 3-$\log_{10}$ is a reasonable expectation.

7.6 Simulated-use test protocol

The following protocol can be used for simulated-use testing:

a) Prepare test soil that is appropriate for the medical device being tested, ensuring that it contains an appropriate bioburden challenge. Ensure that qualified personnel undertake the testing and appropriate biosafety containment guidelines are followed during the test.

b) Determine the method (assay) to be used to recover the inoculate and validate its effectiveness.

c) Soil the device or surrogate by using an inoculation technique that mimics in-use manipulations, by immersing the device in the soil and/or flushing the soil through any channels. Allow the soiled device to dry at room temperature (20 °C to 23 °C (68 °F to 73 °F)) or under other environmental conditions as deemed appropriate. The drying times tested should include a realistic minimum and extended times that reflect possible in-use conditions for the device. For example, a short dry time representative of the usual transit time might be 1 hour to 2 hours, and a long dry time representative of exceptionally long transit time might be overnight.

d) Process a set of replicate devices using the cleaning protocol to be evaluated. Keep one set of soiled devices uncleaned to determine the amount of recoverable soil and bioburden in the absence of cleaning.

e) Collect samples from the test devices by means of destructive methods or, if possible, use *in situ* tests. Indirect sampling may be used if necessary.

f) Ideally, obtain samples and data for each of the following stages (using sufficient replicates to ensure reproducibility):

   1) soiled but not cleaned (positive control for recoverable levels of soil and microorganisms);

   2) soiled and cleaned (but not disinfected and sterilized);

3) not soiled (negative controls).

g) Assay each sample for those soil parameters deemed relevant and the prevalent contaminant encountered in the device after patient use. The limits of detection of all assays used should be stated.

After cleaning benchmarks have been established, it will be possible for manufacturers to validate test device cleaning protocols. In addition, manufacturers should provide users with cleaning tests that can be used to verify continued compliance with the validated cleaning processes and procedures (see 5.4.3).

8 Regulatory considerations

8.1 Overview

Guidance documents regarding the cleaning of reusable medical devices are available from the FDA, regulatory agencies in other countries, and standards organizations.

8.2 U.S. FDA guidance documents

The FDA has issued several guidance documents for industry and for FDA reviewers and compliance staff:

a) *Guidance on the content and format of premarket notification [510(k)] submissions for liquid chemical sterilants and high level disinfectants* (Office of Device Evaluation, Center for Devices and Radiological Health, FDA, January 3, 2000);

b) *Labeling reusable medical devices for reprocessing in health care facilities: FDA reviewer guidance* (Office of Device Evaluation, Center for Devices and Radiological Health, FDA, April 1996);

c) *Guidance for industry: Premarket notification [510(k)] guidance document for contact lens care products* (Office of Device Evaluation, Center for Devices and Radiological Health, FDA, May 1997); and

d) *Class II special controls guidance document: Medical washers and medical washer-disinfectors: Guidance for the medical device industry and FDA review staff* (Office of Device Evaluation, Center for Devices and Radiological Health, FDA, February 7, 2002).

8.3 National guidance documents and standards

Australia and the United Kingdom have published standards that pertain to the cleaning of reusable medical devices:

a) Australian Standard AS 4187:2003, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*;

NOTE—In Section 2, “Cleaning and handling of used items,” this standard covers water quality for cleaning, cleaning agents, cleaning methods, and monitoring of cleaning processes. According to this standard, “effective cleaning ensures that instruments and equipment are clean to the naked eye (macroscopic) and free from any protein residues.” AS 2773 describes the use of ultrasonic cleaners, AS2945 covers washer-disinfectors, AS 2945 addresses batch-type washers, and AS 3836 covers surgical-equipment-rack conveyor washers (tunnel washers).

b) British Standard 2745:1993, *Washer-disinfectors for medical purposes. Part 3. Specification for washer-disinfectors except those used for processing human-waste containers and laundry*; and

c) Health Technical Memorandum 2030:2001, *Washer-disinfectors: Part 3: Validation and verification* (U.K. Department of Health).

8.4 International standards

Pertinent international standards include the following:

a) ISO 14729:2001, *Ophthalmic optics—Contact lens care products—Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses*;

b) ISO 17664:2004, *Sterilization of medical devices—Information to be provided by the manufacturer for the reprocessing of resterilizable devices*;

c) ISO 15883-1 (in development), *Washer-disinfectors, Part 1: General requirements, definitions, and tests*;

d) ISO 15883-2 (in development), *Washer-disinfectors, Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc.*;

e) ISO 15883-3 (in development), *Washer-disinfectors, Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*; and

f) ISO 15883-4 (in development), *Washer-disinfectors, Part 4: Requirements and tests for thermo-labile re-usable devices including endoscopes*.

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ROTH K, REICHL R, RININSLAND H, HEEG P, BUESS G, and MUELLER E. Evaluation of device design, features, and impact of reuse. Abstract. AAMI/FDA Conference on Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, Los Angeles, CA, November 13–15, 1996.

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Annex A
(Informative)

Annotated bibliography on device design

Citation	Contents
ALFA MJ. Safe reprocessing of narrow lumened medical devices. Presented at the First International Meeting of International Federation for Sterile Supply, Petaling Jaya, Malaysia, March 25–29, 2001.	The processing of narrow-lumened medical devices is important, as noted by the recent FDA/CDC alert on serious infections from flexible endoscopic procedures. Types of devices that are difficult to clean include flexible endoscopes (1.2 mm to 5 mm lumen diameter), endoscope accessory devices (e.g., sphinctertomes, cannulatomes with less than 1 mm diameter lumens), biopsy forceps, and laparoscopic devices. For a study of single-use sphinctertomes soiled with artificial soil, the cleaning efficacy of manual and automated systems was compared using various soil component evaluation criteria. It was shown that patient materials gain access to lumens but cannot be adequately removed after use (cleaning requires access). With repeated use, soil and organisms can build up. Disinfection/sterilization may be inadequate, and residual microorganisms may survive.
ALFA MJ, DEGAGNE P, and OLSON N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. *Am J Infect Control*, 1999, vol. 27, pp. 392–401.	Narrow-lumened flexible medical devices present the most significant challenge to adequate cleaning and reprocessing. The assessment of adequacy of cleaning within narrow lumens and other areas that are difficult to access (e.g., hinges and joints) is extremely difficult. Experimental evidence demonstrates that residual sodium ion or protein can interfere with the ability of sterilizers to kill bacteria reliably. The soiling levels of narrow-lumened flexible endoscopes used on patients were assessed for bronchoscopes, duodenoscopes, and colonoscopes. The effect of cleaning on the soil composition and concentration was evaluated. Worst-case soil levels were protein, 115 $\mu g/cm^2$; sodium ion, 7.4 $\mu mol/cm^2$; hemoglobin, 85 $\mu g/cm^2$; bilirubin, 299 $\mu mol/cm^2$; carbohydrate, 29.1 $\mu g/cm^2$; endotoxin, 9852 EU/cm^2; and bacteria, 7.1 log cfu/cm^2. Colonoscopes had four to five times greater soiling on average. Levels of protein, endotoxin, and sodium ion were reduced 5-fold to 10-fold; residual hemoglobin was detectable only in bronchoscopes, and carbohydrate was detectable only in duodenoscopes. Bacteria were reduced from 5.9–9.5 log cfu/channel to 3.2–5.3 log after cleaning. Despite cleaning, there were significantly higher concentrations of residual hemoglobin, sodium ion, protein, endotoxin, and bacteria within the bronchoscope channels. Differences in residual soil may relate to the difference in disinfection/sterilization processing of the scopes at this center. Because the bronchoscope suction channel is shorter and/or less complex than the channels of the other scopes, buildup of soil in bronchoscopes may have occurred that may also relate to the different methods of reprocessing these scopes. Even after routine cleaning, the residual levels of bioburden remaining in the channels were substantially higher than those found either on or within the lumens of rigid easily cleaned devices. This data demonstrated that cleaning effectively reduced or eliminated many components of soil, but a substantial amount of viable bacteria and protein remained. Hemoglobin levels in before samples indicated that blood was not present in high concentrations in the suction channels of the majority of flexible endoscope samples. Soil that mimics the *worst-case* composition from endoscopes used in patients would be ideal for simulated-use studies for such medical devices. For worst-case soiling, full strength Edinburgh soil or Hucker's soil are inappropriately severe challenges for narrow lumened flexible endoscopes.

Citation	Contents
BISSON S, FENGLER TW, PAHLKE H, and MICHELS W. Clinical study design and significance. Abstract. Poster presented at the 7th World Congress of Endoscopic Surgery, Singapore, June 1–4, 2000.	Studies were performed to quantify amounts of protein that can be eluted from visibly clean surfaces of instruments used in clinical routine. Instrument surfaces were eluted with sodium dodecylsulfate, and the solution was analyzed by Sangur for hemoglobin, Biuret for proteins, both calorimetric semi-quantitative methods, and quantitatively with OPA. Of 219 surgical instruments (used in traumatology, gynecology, surgery, and laparoscopy), 200 were visibly clean. Traces of protein were eluted from nearly 50 % of the instruments. Quantities differed from the centers participating and types of instruments. The Sangur test was less specific. Cleaning results depend on different factors, which can be controlled only partly under clinical field conditions. The influence of instrument design can be examined *in vitro*.
BOND WW, OTT BJ, FRANKE KA, and MCCRACKEN JE. Effective use of liquid chemical germicides on medical devices: instrument design problems. In: BLOCK SS, ed. *Disinfection, sterilization, and preservation*. 4ed. Philadelphia: Lea & Febiger, 1991, pp. 1097–1106.	Both the design and manufacture of a number of reusable instruments have centered almost entirely on the intended function of the device, with insufficient consideration given to pertinent questions such as easy physical access to all potentially contaminated components; physical and chemical stability; verifiable methods for cleaning, disinfecting, or sterilizing; and clear adequate instruction materials to ensure safe and effective use of the instruments. Instruments designed to include (in any degree) lumens, crevices, loosely mated or occluded surfaces, knurled or textured surfaces, and fragile (heat-sensitive or easily corroded or abraded) materials present the greatest challenges to effective cleaning and disinfecting or sterilizing. Flexible fiberoptic endoscopes and their accessories, as well as a variety of dental instruments, are among these instruments.
BRESLAWEC H. FDA premarket medical device design reviews. *Proceedings of the Infection Control Symposium: Influence of Medical Device Design*. USDHHS, FDA, January 1995, pp. 43–46.	FDA considers design to be a function of the intended use of the device. One validated reuse procedure must be spelled out in the labeling.
CHAN-MYERS H, MCALISTER D, and ANTONOPLOS P. Natural bioburden levels detected on rigid lumened medical devices before and after cleaning. *Am J Infect Control*, 1997, vol. 25, pp. 471–476.	The degree of microbial contamination, the level and types found on rigid lumened medical devices, and the efficacy of cleaning techniques for removing organisms from lumen channels were studied. The bioburden level after clinical use was low (10^1–10^4 cfu/device). After cleaning, no devices had levels $> 10^4$ cfu, and 83 % had $< 10^2$ cfu. The bioburden before cleaning consisted of organisms derived from the handling of the device, the hospital environment, and the patient. The bioburden after cleaning consisted of organisms derived from the handling of the device and the environment. In some instances, the levels of bioburden were increased or equivalent to the level of bioburden before cleaning (but the organisms were distinctly different). The level of bioburden on the device was also related to the anatomic site where the device was used; low numbers of organisms were on devices used in sterile body sites and respiratory tracts.
CHU NS, MCALISTER D, and ANTONOPLOS PA. Natural bioburden levels detected on flexible gastrointestinal endoscopes after clinical use and manual cleaning. *Gastrointest Endosc*, 1998, vol. 48, pp. 137–142.	The bioburden of colonoscope insertion tube surfaces and of suction channels was determined after use and after manual cleaning. These devices contain physically complex internal structures with multiple long and narrow lumens, and this geometry can impede cleaning, disinfection, or sterilization. After use, bioburden in suction channels was 7.0×10^9 cfu; cleaning reduced this level to 1.3×10^5 cfu. Cleaning of tube surfaces reduced the after-use bioburden from 5.1×10^5 cfu to 2.2×10^4 cfu. After use and after cleaning, 99 % of the bioburden in the suction channel consisted of Gram-negative rods. After use, flora were predominantly *E. coli* and *Bacteroides*. After cleaning, flora were waterborne *Pseudomonas* organisms, *Enterobacteriaceae*. Gram-positive organisms were isolated on the device surfaces after use (56 %) and after cleaning (47 %). After cleaning in-use colonoscopes, $< 10^6$ vegetative bacteria were recovered.

Citation	Contents
DEMPSEY KM, CHIEW RF, MCKENZIE JA, and MITCHELL DH. Evaluation of the cleaning and disinfection efficacy of the DEKO-190; a ward-based automated washer/disinfector. *J Hosp Infect*, 2000, vol. 46, pp. 50–54.	This automatic ward-based combined washer-disinfector is used to decontaminate ward items (bedpans and urine bottles) and instruments before sterilization. Microbiological evaluation of the disinfection efficacy of the machine yielded total inactivation of *E. faecalis* and polio virus. Counts of aerobic organisms (in a stool specimen) were reduced by 10^4, and spores of *C. perfringens* were unaffected. The cleaning efficacy was evaluated by visual inspection and was satisfactory. Clamps, not opened before placement into the machine, had minute amounts of material in the hinged region. Hinged or ribbed instruments such as forceps or clamps are particularly difficult to clean adequately, even by manual scrubbing.
DESCOTEAUX J-G, POULIN EC, JULIEN M, and GUIDOIN R. Residual organic debris on processed surgical instruments. *AORN J*, 1995, vol. 62, pp. 23–29.	The degree of cleanliness of reusable laparoscopes, reused disposable laparoscopes, and conventional surgical instruments after processing (i.e., decontamination, inspection, sterilization) was studied. For 32 instruments, 90.6 % were clean on visual inspection. Microscopic examination revealed residual debris on 84.3 %. The quantity of residual debris on both types of laparoscopic instruments was equivalent. Conventional instruments contained less residual debris. The sites of residual debris included junctions between insulating sheaths and activating mechanisms of laparoscopic instruments and articulations and grooves of forceps.
DIETZE B and MARTINY H. Validation of washer-disinfectors. *Zentr Steril*, 1997, vol. 5, pp. 267–272.	Instruments subjected to manual and/or automated processing must undergo a validated process to guarantee results. The design of the washer-disinfector is part of the validation process, as is the extent to which the cleaning and disinfection has been performed. Efforts are being made (by DIN, CEN, ISO) to examine efficacy of cleaning and disinfection methods to be standardized. Adequate cleaning is required for sterilization. The diversity of the instruments, soil, and method of cleaning are all issues that need to be investigated. A quantitative method for determining clean is mandatory.
DIETZE B, KIRCHEIS U, SCHWARZ I, and MARTINY H. Freely accessible endoscope channels improve efficacy of cleaning. *Endoscopy*, 2001, vol. 33, pp. 523–528.	Study investigated the influence of the medical device design on the efficacy of manual cleaning of endoscope channels. Duodenoscopes and gastroscopes were studied. The rate of microorganism recovery from air/water channels by flushing was a maximum of 3 % relative to the rate detected after brushing and flushing. Only flushing channels that are not freely accessible resulted in significantly lower recovery rates of the test organism. Channels of endoscopes that are not freely accessible are very difficult to clean.
FENGLER TW, PAHLKE H, MICHELS W, BISSON S, and KRAAS E. (Chirurgie-Instrumenten Arbeitsgruppe Berlin). How clean are sterile instruments? Symposium of the World Federation for Central Service in Hospitals, Orlando, FL, May 16–20, 1999.	Parameters for cleaning efficacy were evaluated on laparoscopic instruments. Device design, function, ultrasonics, and washer-disinfector fluid flow all influenced the results. Visual methods are still the standard to detect contamination on instruments. Significant differences correlating to surface roughness and the construction of shafts (specifically, the ability to be dismantled) were measured. Results for sharp and blunt working tips showed different cleanability. More than half of the working tips of bipolar forceps still had visual residues after automated cleaning. Instruments that could be disassembled were easier to clean, as were smooth surfaces. More than 95 % of residues could be regained from instruments with capillary gaps (except for meniscus forceps that could not be disassembled). Validation of automated cleaning with washer-disinfectors should depend on measurement of process parameters.

Citation	Contents
FENGLER TW, BISSON S, PAHLKE H, FRISTER H, and MICHELS W. Multicenter study on clean instruments. Poster presented at the 7th World Congress of Endoscopic Surgery, Singapore, June 1–4, 2000.	A multicentric (five central sterile supply departments) clinical observational study was conducted on six typical surgical instruments from surgery (Wertheim forceps), traumatology (rasparatorium), laparoscopy (forceps inlet, trocar valve, trocar sleeve), and gynecology (speculum). Visibly clean surfaces were rinsed with sodium dodecylsulfate and analyzed for protein by Sangur test for hemoglobin and by modified Biuret test and OPA method. Proteins were found in small amounts in the eluate of nearly half of the instruments and could not be related to a specific instrument design. Recovery from an instrument's surfaces varies and will never be 100 %. Cleaning results depend on different factors. Optimization of instrument design and configuration of washers-disinfectors depend on a precise measurement of cleaning efficacy. A cleaning indicating system should be based on protein detection as the most relevant contamination.
FENGLER TW, PAHLKE H, BISSON S, MICHELS W, and KRAAS E. Regaining soils from instrument surfaces: SDS-OPA method with native blood as contaminant. Abstract. Poster presented at the 7th World Congress of Endoscopic Surgery, Singapore, June 1–4, 2000.	Reusable surgical instruments might have certain adhesions on their surfaces that are difficult to detect. Elution of the surfaces leads to a percentage of recovery of test soils, the amount of which depends on different parameters, from the chemical nature of the detergent to the design of surface properties and biological nature of the soil/debris. Glass and steel plates were contaminated with native blood and then dried. The following day, they were eluted with sodium dodecylsulfate and assessed photometrically with OPA. Recovery was greater than 95 % in the range where the contaminant blood was not visible but still present (µL blood per mL eluate). The OPA method was sensitive, specific, and reproducible, but the test method has limitations concerning daily use in clinical sterile supply. The design influence for arthroscopy forceps was shown, with cleaning efficiency near complete for the instruments that could be disassembled, as opposed to those that could not be disassembled. Larger but smoother surfaces will retain less soil than smaller but less smooth surfaces. Proneness to soiling and cleanability are closely related. A quick test device to assess the cleaning stage as part of the overall decontamination effort would be highly welcome.
FENGLER TW, PAHLKE H, BISSON S, MICHELS W, and KRAAS E. How clean are sterile instruments? Parameters—Testing—Clinical data. Proceedings of the EUROMAT, International Congress on Advanced Materials and Processes, Munich, September 27–30, 1999. In: *Materials for Medical Engineering*, vol. 2, Stallforth, 2000.	Tracer instruments (*in vivo*), test soils, and test probes (*in vitro*) are needed to examine surface layers that might contain infective material. Disinfection efficacy, including reduction of colony-forming units, must be distinguished from the dynamics of cleaning, where a minimum of any surface-covering material must be reached to avoid camouflaging hiding microorganisms. *In vivo* testing of clinically used instruments is important in determining the levels of cleanliness that are adequate for sterile processing. *In vitro* testing allows evaluation of the parameters of cleanability. In *in vitro* testing, a minimum value of layer thickness must be achieved, instead of a reduction factor as for microorganisms. Proteins are the most clinically significant contaminant. Measurements directly on the surface are time-consuming. Measurements in the eluate allow the collection of clinically relevant data.
FRIEDEN J. Human error needs consideration in device design. *Reuters Health (On Line)*, February 20, 2001. <http://www.reutershealth.com>	Designers need to take three factors into account when designing a product: the type of people who will be using it, the environment in which it will be used, and how the user will interact with the device. When any of these factors is ignored, errors can result. A great number of extraordinary deaths are injuries due to misuse of medical devices by people doing things with them that engineers never thought anyone would do. It is estimated that even if hospital staff members were 99.9 % reliable, at least 1 million medication errors would still be made annually. Despite the large need for better device testing, many manufacturers are reluctant to do such tests because they think they will cost too much. Devices that are easy to use can greatly help reduce errors.

Citation	Contents
FRISTER H and MICHELS W. Comparative assessment and optimisation of the cleaning performance of automated decontamination processes. *Hygiene Medizin*, 1994, vol. 19, pp. 673–688.	Thorough cleaning is necessary to decontaminate instruments. Cleaning and disinfection should be standardized independently of each other for quality assurance. Relevant parameters of cleaning (time, temperature, detergent) should be evaluated to create the best possible processing method. Cleaning performance was evaluated and optimized using a blood-contaminated porous borosilicate filter together with the modified OPA protein analysis method. Cleaning efficacy in automated decontamination processes can be standardized and periodically monitored using this method. Such a test is particularly needed in the case of long, narrow, inaccessible orifices such as those used on flexible endoscopes and in the handles of take-apart MIS instruments (forceps, etc.).
GRIFFITH CJ, COOPER RA, GILMORE J, DAVIES C, and LEWIS M. An evaluation of hospital cleaning regimes and standards. *J Hosp Infect*, 2000, vol. 45, pp. 19–28.	This study assessed the cleanliness of 113 environmental surfaces in an operating theater and hospital ward. Surfaces were assessed visually, by microbiological methods, and by ATP bioluminescence. Results from a preliminary random survey indicated variability in cleanliness. Those results were then used to select sites for monitoring before and after routine cleaning, over a 14-day period. Using published microbiological and ATP specifications, 70 % to 76 % of these sites were unacceptable after cleaning. Visual assessment was a poor indicator of cleaning efficacy, with only 18 % considered unacceptable. Operating theater sites had lower ATP results, but 61 % of sites would be considered unacceptable. The results are discussed in relation to infection control, cleaning audits, and cleaning schedules; an integrated cleaning monitoring program using ATP bioluminescence in conjunction with visual and microbiological assessments is recommended.
HEEG P. Effectiveness study of a low temperature liquid sterilization process using peracetic acid. *Zentr Steril*, 1999, vol. 7, pp. 18–29.	So that designs for sterilization could be assessed, sites were contaminated that were considered to be most difficult for access of solutions, such as hinges, depressions, or joints with gaps, as well as ribbed or otherwise “roughened” surfaces, jaws and irrigation channels, and lumens. Areas with visible surface damage such as scratching and corrosion, including rusting, could be problematic. Medical products to be processed should be in good condition and free of damage such as corrosion, cracks, or other material flaws.
HIGASHI J, WANG I-W, and MARCHANT R. Material considerations for reusable devices. Abstract. AAMI/FDA Conference on Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, Los Angeles, CA, November 13–15, 1996.	The adhesion of *S. epidermidis* to biomedical polymers used in semicritical cardiovascular devices was examined. Increased surface energy (i.e., wettability) reduced bacterial adhesion. The contribution of surface energy as a determining factor in bacterial adhesion is attenuated at higher shear stresses and by rough surface topography. Topography can be the dominant material property controlling bacterial adhesion irrespective of the material surface chemistry.
KRÜGER S. Testing the cleaning efficacy in decontamination equipment. *Zentr Steril*, 1997, vol. 6, pp. 333–344.	New developments and harmonization of requirements call for standardized verification methods for automated cleaning and disinfection. Verification of cleanliness is of prime importance. The Biuret method (semiquantitative, colorimetric) was used to detect blood and protein residues on instruments. The limit of detection for this assay is 55 µg of protein. This detection method does not detect all possible residues, as SDS is used as the extraction medium. Two different test soils were also used. Sixty surgical instruments subjected to the cleaning and disinfection process were investigated. (They were selected because they featured visible residues or had lumens that could not be inspected by optical means.) Fifty showed level 1 color changes (visible residues or surface alterations that were not protein-containing substances), two showed level 3 changes (visible dark red incrustations), and one showed level 4 changes (rust incrustation).

Citation	Contents
LIPP MD, JAEHNICHEN G, GOLECKI N, FECHT G, REICHL R, and HEEG P. Microbiological, microstructure, and material science examinations of reprocessed Combitubes after multiple reuse. *Anesth Analg*, 2000, vol. 91, pp. 693–697.	Reprocessing (repeated cleaning, disinfection, and sterilization) and reusing single-use Combitube airway devices for emergency endotracheal intubation are possible and can be performed appropriately and safely. Microbiological, microstructure, and material science examinations were performed. Reprocessing consisted of cleaning, disinfection, inspection, and sterilization. Microbiological examinations of reused and reprocessed Combitubes found no test organisms. Microstructure analysis demonstrated nonsignificant alterations between new and reprocessed medical devices. Material testing showed that cuff burst pressures were unaffected. A quality management system must be established, and only validated methods should be used.
MACKCOW JA and PAULY DV. Determination of the efficacy of cleaning methods in the processing of reusable medical devices. *Biomed Instrument & Tech*, 1998; vol. 32, p. 436.	Manufacturers are responsible for providing validated cleaning instructions for reusable medical devices. No guideline or standard of acceptable log reductions for cleaning currently exists. The study covered 216 devices (9 different designs) and used test soil with spores. The manufacturers' cleaning instructions were followed. Log reductions of 3.51–5.43 were attained. The complexity of the device and the cleaning method used affected the ability to reduce the spore load. Cleaning instructions must be specific and appropriate for the device design.
MAKI D. Epidemiology and prevention of intravascular device-related infections. *Proceedings of the Infection Control Symposium: Influence of Medical Device Design*. USDHHS, FDA, January 1995, pp. 27–34.	The problem of device-related infection is that the risk of infection, in contradistinction to most other types of serious nosocomial infections, is influenced relatively little by the underlying disease. The single most important determinant of risk of infection is the type of device that is used. Central venous catheters account for about 90 % of all blood stream infections caused by devices.
MALCHESKY PS, CHAMBERLAIN VC, SCOTT-CONNOR C, SALIS B, and WALLACE C. Reprocessing of reusable medical devices. *ASAIO J*, 1995, vol. 42, pp. 146–151.	Device designs should be readily amenable to cleaning and sterilization. In the past, design requirements focused primarily on the clinical user, and device functionality with reuse considerations was left to the user. Device designs must be suitable for reprocessing. Regulations now require that manufacturers give detailed instructions for reprocessing devices. It is up to the clinician to ensure quality control during reprocessing. Close cooperation between users of those devices and manufacturers will best ensure continued responsible development of the field. Medical devices such as flexible endoscopes should be designed to allow easier cleaning through the elimination of acute angles and rough, porous, or occluded surfaces. Device designs must meet total acceptance from the viewpoints of the surgeon, or physician, other associated health care practitioners, and the medical procedure payer. The customer is no longer just the physician or surgeon but must include all participants in the customer's operation from receiving, storage, recordkeeping, functionality, and fitness for use through reuse processing. The responsibility for reuse is shared, with the manufacturer providing the information and the health care facility performing the process. Newer laparoscopic instruments incorporate flushing parts and take-apart models to make them easier to clean. Many devices now can be disassembled easily for cleaning. Joints and lumens should be minimized and made accessible to cleaning. Stainless steel can be subject to pitting and stress corrosion cracking and can harbor bacteria. Shrink tubing or coatings can crack and provide moist breeding grounds. Designers should be familiar with the reuse process to develop the best design for functionality and cleanability. Validation of cleaning methods should incorporate standard hospital equipment and contamination levels and be performed on a simulated worst-case basis, with microbiologic challenge and sterility testing.

Citation	Contents
MALCHESKY PS, TATALICK JW, BELL JS, and KRALOVIC RC. A model program for reusable medical device testing. *Med Dev & Diag Ind*, June 1994, vol. 16, pp. 190–194.	A device testing program is described to provide scientific data on devices for reuse using vigorous, standardized test protocols. The program includes sterilization evaluation with spores and material compatibility testing.
MARLOW SC and PETRUSCHKE HK. Cleanability of hybrid laparoscopic instruments. *AORN J*, 1995, vol. 62, pp. 32–36.	A cleaning protocol was established and implemented to determine whether hybrid laparoscopic instruments (incorporating a reusable handle and shaft and push-rod assembly with a twist-lock connection, handle screw and seal, and a single-use jaw) can be cleaned effectively before sterilization. Instruments were soiled under pressure with defibrinated sheep blood to simulate an abdominal laparoscopic surgical procedure (i.e., creating a pneumoperitoneum). After cleaning, visual and optical inspections of the instruments indicated that all were free of visible soil. It was concluded that a hybrid laparoscopic instrument system could be cleaned satisfactorily before sterilization.
MERRITT K, HITCHINS VM, and BROWN SA. Safety and cleaning of medical materials and devices. *J Biomed Mater Res (Appl Biomater)*, 2000, vol. 53, pp. 131–136.	Procedures to remove microorganisms, protein, and cells from medical device materials and a method for cleaning and validating cleanliness for reuse or failure analysis were evaluated. 96 well plates were used to simulate device surfaces not amenable to manual cleaning. *S. epidermidis*, *C. albicans*, *E. coli*, *P. aeruginosa*, and oral flora were grown in the polystyrene plates and stained with crystal violet, and OD was measured. *E. coli* did not adhere well, and *Pseudomonas* clumped and was easily detached. *S. epidermis*, *C. albicans*, and oral flora formed adherent biofilms that were difficult to remove. Detergents with enzymes and NaOCl were both effective in removing biofilm. Other detergents and surfactants were not effective. The aldehydes did not remove the organisms and made further cleaning difficult. Allowing the biofilm to dry made cleaning very difficult; only NaOCl could remove the dried or aldehyde-fixed organisms. Protein and cell adherence were also measured. NaOCl was effective at removing dried or fixed protein and cells; detergent with enzymes was not effective. Medical devices contaminated with microorganisms, protein, and/or mammalian cells should not be allowed to dry before cleaning, and a thorough cleaning procedure should precede sterilization or disinfection (with the exception of NaOCl, which also cleans).
MIELNIK TJ. Materials and design issues impacting on cleanability of devices. *Proceedings of Infection Control Symposium: Influence of Medical Device Design*. USDHHS, FDA, January 1995, pp. 208–217.	A device that is designed to be cleaned easily is also relatively easy to disinfect or sterilize. The instrument should be designed with a recommended cleaning and decontamination process in mind. Overlapping or butted joints that create inferior angles formed by two meeting walls can create a harbor for contamination. The preferred design configuration at a joint or interface should provide a smooth transition surface between meeting walls. Fissures that are of considerable depth and length can impede the penetration of a cleaning agent and should be eliminated. Proper design will also ensure that a crack or crevice will not develop naturally over time because of normal use and reprocessing conditions. A surface that is porous may present a more difficult challenge for cleaning. Devices that are smooth in texture will be easier to clean. Overlapping, tightly fitted contact areas must be able to be taken apart. Consideration should be given to minimizing adverse flow conditions in the instrument that would compromise the delivery of the cleaning agent. Complex internal plumbing configurations with multiple changes of flow direction, dead-headed flow parts, exceptionally small fluid channels that can easily clog with debris, and so forth, should be eliminated from the design where possible.
MILES RS. What standards should we use for the disinfection of large equipment? *J Hosp Infect*, 1991, vol. 18 (suppl A), pp. 264–273.	There are no universal guidelines for cleaning and disinfecting large items of medical equipment. Washer-disinfectors provide one method of making medical equipment safe. Evaluating the performance of such machines is discussed, to review existing advice and guidelines on cleaning and disinfection. Interested parties should agree on practical standards for the cleaning and disinfection of medical equipment using washer-disinfectors. Joints, channels, crevices, and blind ends all present difficult problems.

Citation	Contents
MILES RS, WOLFE R, MALCOLM-SMITH N, and BOWICK G. Evaluation of the Draeger anaesthetic equipment washing machine (ANDA 9002). *J Hosp Infect*, 1989, vol. 13, pp. 399–411.	An anesthetic equipment washing machine was evaluated using artificial soil (Edinburgh and Collins & Connelly) to determine cleaning efficacy. No standardized time/temperature profile is agreed upon for anesthetic equipment. The cycle included a 5 min wash (70 °C), 3 min rinse (90 °C), and 30 min drying. A clean, dry, disinfected load could be produced within 75 min. In 48 machine cycles tested, only three failures were noted—traces of soil on an amber mask at the junction of the body and the detachable pneumatic cuff. The time and temperature deteriorated some materials of the anesthetic equipment.
MOSTAFA ABMG and CHACKETT KF. Cleaning of surgical instruments: a preliminary assessment. *Med Biol Engin*, September 1976, vol. 14, pp. 524–527.	Assessments were made of techniques used for cleaning surgical instruments using radioisotope methods with instruments soiled with human serum albumin labeled with Technetium 99m. Cleaning efficiency varied with the kind of instrument: polypropylene instruments were cleaned more easily than stainless steel ones; instruments with serrated surfaces, joints, or hinges were difficult to clean. Corroded serrated surfaces, joints, or hinges are difficult to clean. Corroded serrations and cavities near the hinges of worn joints in scissors and forceps retained soil. Soil retention correlated with the microscopic state of the instrument surfaces. Cleaning of instruments on which the soil had not been allowed to dry was invariably better than if the soil had dried.
NYSTRÖM B. Thoughts on levels of microbial cleanliness and on validating disinfection procedures. *J Healthc Mater Mgmt*, 1993, vol. 11, pp. 14–24.	Efforts of the CEN and the ISO to harmonize production standards for medical devices highlight the need to standardize definitions and names for different levels of microbial contamination and standardize validation procedures for microbial inactivation. Spaulding's categories of medical devices (critical, semicritical, noncritical) suggest that different levels of cleanliness can be accepted. Current terminology is imprecise and does not provide the necessary information to the user. More appropriate terminology is needed, as are methods to validate microbial inactivation processes to lower levels of cleanliness than sterility. International standards on disinfection are lacking. Acceptable levels of contamination for disinfected devices remain to be established.
PETERSON LL and MACKCOW JA. A cleaning effectiveness study for reusable medical devices. *Biomed Instrument & Tech*, July/August 1997, vol. 31, p. 332.	Manufacturers of reusable medical devices are responsible for providing validated cleaning instructions to their customers. Artificial soil inoculated with nonpathogenic spores was applied to devices to simulate clinical conditions. *B. stearo* at 10^4–10^5 in fetal calf serum, powdered milk, and a 1:1 blood-saline mixture made up the test soil. Devices were dried to create worst-case conditions. Devices were cleaned per manufacturers' instructions. A 4-log reduction of spores was achieved through the cleaning process.
PFEIFER M. Standardized test soil for testing the cleaning efficiency of washer/disinfectors. Abstract. AAMI/FDA Conference on Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, Los Angeles, CA, November 13–15, 1996.	Cleaning before disinfection or sterilization should be monitored. A clinically relevant standardized test soil was not yet available. This test soil is based on blood coagulation, a two-part system consisting of fibrinogen and thrombin. This soil takes into account the chemical and physical influence of soil on cleaning.

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PFEIFER M. Blood as a soil on surgical instruments: Chemical profile, cleaning, detection. *Zentr Steril*, 1998, vol. 6, pp. 381–385.	Surgical instruments require standardized and validated reprocessing. Procedures generally consist of cleaning and disinfection in a washer-disinfector followed by steam sterilization. Cleaning failures cause devices to be reprocessed. Blood is the most common contamination form. Blood components are mostly water soluble, with the exception of fibrin, which causes coagulation. The protein content of blood is also very important. Testing done with human blood would be variable, so a standardized test soil is vital to the quantification and verification of cleaning processes. Heat in conjunction with water coagulate and harden blood proteins, and detergents do not dissolve fibrin. Hydrolysis used in conjunction with ultraviolet absorption provides a reliable method for quantifying residual proteins on medical devices.
PFEIFER M and HEEG P. Test object surgical instruments: Monitoring of the cleaning efficacy of washer-disinfectors. Technical literature, September 1999. PEREG GmbH.	Sterilization cannot be carried out if organic contamination is present. Cleaning efficacy before sterilization is of utmost importance and must be monitored. A device is presented that simulates a surgical instrument contaminated with a standardized test soil. The cleanability of this device correlates to that of surgical instruments, offering a visual method of assessment of the cleaning process (mechanical, detergent action).
PRATT LH, SMITH DG, THORNTON RH, SIMMONS JB, DEPTA BB, and JOHNSON RB. The effectiveness of two sterilization methods when different precleaning techniques are employed. *J Dent*, 1999, vol. 27, pp. 247–248.	Dental handpieces were cleaned before undergoing ethylene oxide (EO) sterilization by using a forced-air purging unit or flushing with air and water from the dental unit. They were inoculated with either *B. subtilis* or *S. mutans*. After exposure to either steam or EO, the handpieces were assessed for viable organisms. After either EO or steam sterilization, no viable bacteria were recovered from handpieces cleaned with forced air. However, viable *S. mutans* were recovered from air/water flushed handpieces after EO. A high-pressure forced-air purging unit may be required for reliably sterilizing dental handpieces by EO.
REICH RR and OTTNEY RM. Validating bioburden recovery techniques. *Med Dev & Diag Ind*, November 1992, vol. 14, no. 11, pp. 88–94.	A study was undertaken to evaluate the efficiency of commonly used extraction methods for recovering mesophilic bacteria from substrates. The most effective extraction method for bioburden recovery varies according to the substrate (stainless steel, gauze, PVC tubing, silicone tubing).
REICHERT MF and SCHULTZ JK. Infection control in endoscopes. In: BLOCK SS, ed. *Disinfection, sterilization, and preservation*. 5ed. Philadelphia: Lippincott Williams & Wilkins, 2001, pp. 967–977.	Gastrointestinal endoscopes, with their multiple internal channels and valves, are more complex than the single-channeled bronchoscopes. The more complex the instrument—the more crevices, joints, or surface pores there are—the more problematic cleaning and disinfection becomes. The elevator wire channel in the side-viewing duodenoscope is one of the most difficult areas to clean. The design of reusable devices must permit adequate cleaning along with penetration and removal of sterilant or high-level disinfectant. Designs that inhibit cleaning include metal-on-metal fittings with very close tolerances. Devices with lumens should be designed for disassembly or include flush parts to allow adequate access to the lumen.
REICHL R, INACKER O, ROTH K, SCHRIMM H, SIEBER JP, HEEG P, and BUESS G. Identification and quantification of surface contamination on surgical instruments with surface analytical methods after cleaning procedures. *Minim Invasive Ther*, 1995, vol. 4, pp. 319–339.	Cleaning procedures for long-lumened devices (e.g., laparoscopes) have no quantifying analytical method to control contamination on the instruments. X-ray photoelectron spectroscopy (XPS) provides quantitative data on the elemental composition of surface and interior contamination of a lumened device. A needle holder was contaminated. XPS showed that, despite cleaning, there was nonhomogeneous contamination of the shaft. Evaluation of a variety of devices defined a standard for “clean” and a procedure to validate that the standard is met. This method can be used as a reference to develop easier methods to detect contamination.

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REICHL R, ROTH K, RININSLAND H, HEEG P, BUESS G, and MÜELLER E. Optimization of device design, topography and chemical composition of inner and outer surfaces on minimally invasive surgery (MIS) instruments. Abstract. AAMI/FDA Conference on Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, Los Angeles, CA, November 13–15, 1996.	Current methods for reprocessing MIS instruments are labor- and cost-intensive. Efficient and safe processing will be achieved through the combination of instrument design and surface modifications of the instruments (chemical, topographical). A cooperative project was started with device manufacturers, materials manufacturers, and washing machine producers to optimize the cleanability of MIS instruments.
REICHL R, BECKMANN P, DREHER WF, INACKER O, MUELLER E, HEEG P, ROTH K, and BUESS G. Innovations in medical technology based on surface and interface analytical methods (Parts 1 and 2). *Zentr Steril*, 1998, vol. 6, pp. 222–231, 388–400.	The functional capabilities and quality of surgical instruments are, to a large extent, governed by their surface characteristics. Surfaces of surgical instruments were examined after reprocessing. Methods discussed for examination included scanning electron microscopy, photoelectron spectroscopy, secondary ions mass spectroscopy, and secondary neutral mass spectrometry. Smooth surfaces are easy to clean.
ROTH K, SIEBER JP, SCHRIMM H, HEEG P, and BUESS G. Automated reprocessing of endoscopic surgical instruments. *Endosc Surg Allied Technol*, 1994, vol. 2, pp. 279–281.	Test procedures were developed to validate the automated processing of endoscopic surgical instruments, so that the cleaning results are guaranteed and reproducible. A device for testing and cleaning was designed, which automated processing and reduced manual work. Parameters that are vital to cleaning are rinsing time, temperature, quantity, and chemical additives. This method of evaluation is suitable for experimental use but not for clinical use because it uses radioactive substances.
ROTH K, HEEG P, REICHL R, and BUESS G. A new method for evaluation and validation of the cleaning process. Abstract. AAMI/FDA Conference on Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, Los Angeles, CA, November 13–15, 1996.	Control of the cleaning process is done macroscopically. Visual control of all surfaces of instruments is not possible. This procedure verifies the cleaning and decreases the costs of reprocessing. The procedure involves contaminating the devices with radiolabeled blood in a pressurized box (simulating the abdomen). After cleaning, the interior of the instruments was inspected with a gamma camera, and remaining contamination was seen. Both instrument and washer-disinfector manufacturers modified existing processes or designed new products on the basis of the cleaning validation data provided by this testing.
ROTH K, REICHL R, RININSLAND H, HEEG P, BUESS G, and MÜELLER E. Evaluation of device design, features, and impact of reuse. Abstract. AAMI/FDA Conference on Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, Los Angeles, CA, November 13–15, 1996.	Construction of MIS instruments inhibits successful reprocessing. Some do not allow a secure attachment of the rinsing system to the rinsing port because of missing Luer-Lok adaptors. For others, the location of the Luer-Lok hinders the rinsing of instruments with open jaws. The best position of the Luer-Lok was evaluated using the radionuclide method.

Citation	Contents
ROTH K, HEEG P, REICHL R, COGDILL P, and BOND W. Quality assurance on reprocessing accessories for flexible endoscopes—Just how clean are cleaned instruments really? *Zentr Steril*, 1999, vol. 7, no. 2, pp. 84–96.	The efficacy and safety of manual procedures for reprocessing artificially contaminated endoscopy accessories were investigated using the radionuclide method and microbiological procedures. Neither adequate cleaning nor adequate disinfection was achieved in the majority of the multiple- and single-use medical devices inspected. The study demonstrated that often the design of the instruments impeded reliable reprocessing. Manufacturers' instructions for reprocessing reusable instruments were inadequate. None of the inspected instrument types could be reprocessed reliably and safely. This failure was attributed less to inadequate cleaning technique than to the instrument design. Forceps should be designed so that the internal lumen can be cleaned. Adequate cleaning cannot be assumed from good disinfection results. Because of design features, effective quality assurance is currently not possible when reprocessing endoscopy accessories.
ROTH K, HEEG P, REICHL R, and BUESS GF. Validation of the cleaning stage. Center for the Testing of Medical Products PMP. March 7, 2001.	Cleaning is a prerequisite for disinfection and sterilization. This study evaluated the reprocessing of reusable and single-use devices reprocessed under simulated-use conditions. Cleaning efficacy is traditionally measured only with microbiologic methods. This study evaluated cleaning, disinfection, and sterilization separately using five methods: radiolabeled macroalbumins, microscopy, scanning electron microscopy, X-ray, and microbiological methods. Validation of cleaning cycles requires three steps: validating device design parameters that affect cleaning, monitoring routine procedures, and periodic testing. The reprocessing of devices must be seen as a system. Device design, cleaning agent, and cycle parameters all work together. The position of the Luer-Lok adapter has to be chosen carefully; the free area inside the shaft of the MIS-device has to correlate with the diameter of the inlet and outlet. Surface roughness and coatings can also affect cleanability. This study showed that only 15 of 57 devices claimed to be sterile were, in fact, sterile and that neither the reusable devices nor the single-use devices met the AAMI TIR12 guidelines after reprocessing. The study concluded that automated, validated cleaning methods for medical devices must be mandatory for hospitals. The cycle must be specific to the device, the washer-disinfector, and the chemistry, and deviation from the cycle parameters must be detected.
RYAN P. Concepts of cleaning technologies and processes. *J Healthc Mater Mgmt*, November/December 1987, vol. 5, no. 8, pp. 20–27.	Cleaning is defined as the removal of all adherent visible soil from surfaces, crevices, serrations, joints, and lumens that prepares an items for safe handling and/or disinfection and sterilization. Cleanliness is measured in two main ways: (1) by visual inspection with the unaided eye or some method of magnification, and (2) by wiping with a fresh towel and checking it for residual soil.
SALIS B. Designing hand-held instruments for reuse. *Proceedings of Infection Control Symposium: Influence of Medical Device Design*. USDHHS, FDA, January 1995, pp. 205–207.	Stainless steel processing must be designed in a manner to avoid potential pitting and cracking, not just for functionality, but also to avoid harboring bacteria. Some of the insulating materials available in the form of shrink tubing may shrink and crack during autoclaving, leading not only to a potential for injury through electrical leakage, but also to the harboring of bacteria. The real design challenge as it relates to infection control is the minimizing of joints and lumens. Joints, serrations, and other cuts in the metal should be accessible and easy to clean. Ronguers are hard-to-clean instruments. Lumens present a challenge. For laparoscopic instruments, the best option may be instruments that can be disassembled for cleaning and reassembled prior to use. With take-apart instruments, the risk is in small parts getting lost or the instrument not being assembled fully or correctly. Cleaning methods should be validated and communicated to the user through labeling and training.

Citation	Contents
SCHRIMM H, SIEBER JP, HEEG P, ROTH K, MUELLER-SCHAUENBURG W, KELLER K-D, and BUESS G. A new method for validating and verifying the cleaning of tubular instruments. *Zentr Steril*, 1994, vol. 2, pp. 313–324.	Reprocessing should be automated, standardized, validated, and documented. Using a nondestructive test method (radionuclide-labeled blood), cleaning of test contamination was measured quantitatively and topographically. The design, material, composition, and irrigation of lumens affect the ability to clean the instrument. To guarantee cleaning, a device must have the following design features: ability to irrigate with high pressure, defined outlets for selective irrigation of functional components, no loss of flow pressure to other regions of the device, disassembly of the device if unable to flow, few joints, and coordinated materials (surface roughness, transitions, niches, etc.). Particular (lumened) instruments that cannot be disassembled and do not feature an irrigation channel exhibit nonremovable internal contamination. The size and location of the irrigation openings in the vicinity of the instrument jaws are vital parameters, as is the tightness of the instruments in the vicinity of the handle. Inadequate cleaning may compromise sterilization, allows pyrogen substances to remain, and leads to erosion of functional capabilities and shortening of service life.
SPACH DH, SILVERSTEIN FE, AND STAMM WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med*, 1993, vol. 118, pp. 117–128.	The more complex the instrument—the more crevices, joints, or surface pores there are—the more problematic cleaning and disinfection become. Because of complex physical arrangements of various channels and valve systems, endoscopes may remain contaminated despite effective cleaning and disinfection. Small channels (1 mm to 1.2 mm internal diameter) cannot be cleaned by physical means and require flushing with liquids or air. Within the endoscope, lumens, crevices, joints, pores, and loosely mated or occluded surfaces are areas that may collect patient material.
STUDY GROUP HYGIENE IN MINIMALLY INVASIVE SURGERY. Recommendations on the automated cleaning and disinfection of rigid instruments in minimally invasive surgery. *Zentr Steril*, 1995, vol. 3, pp. 21–25, 173–177.	In accordance with the Medical Devices Act, surgical instruments must be prepared with a validated procedure. This requirement can be met only by automated reprocessing, where the flow of cleaning solution is ensured and verified. Manual reprocessing cannot be validated. Instruments that cannot be disassembled and do not feature an irrigation adapter may no longer be used, because the lumen cannot be cleaned and sterilized effectively. Instruments that have an irrigation adapter (female Luer-Lok recommended) offer the possibility of internal cleaning. Take-apart instruments must be disassembled for cleaning. The disassembly must be designed so as to improve the cleaning. Instruments should be designed so that all surfaces, both interior and exterior, can come into contact with the cleaning or disinfecting solution. Even where external cleaning and disinfection are performed in conventional automatic washers, this processing modality must be categorized as manual processing, because the manual component involved in cleaning the instrument lumens is significant.

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TATALICK J. Design criteria for reprocessing. Abstract. AAMI/FDA Conference on Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, Los Angeles, CA, November 13–15, 1996.	The probability of a medical device actually being safe after reprocessing is directly related to the ease with which the device can be reprocessed. Any surface that could become contaminated with patient material should be able to be accessed for mechanical cleaning and liquid flow contact. The author discusses his company's device testing program, which provides data for use in design verification in the construction of medical devices. Examples of design features are given. Attachments that cover surfaces should be removable. Electrical buttons should be of the membrane panel type that does not allow surface areas to become uncovered when the button is pressed. Mechanisms that slide over other parts should be opened up to allow adequate clearance between the parts or provide openings for reprocessing tools such as a Luer-type fitting to be introduced or attached. The surface area around fastening devices of hinged joints should be reduced or eliminated. A smooth surface without slots, recessed channels, or grooves allows more consistent reprocessing results. Devices that cannot be disassembled can be improved by the addition of access parts, but too many parts may present other reprocessing difficulties. Stopcocks need to be dismantled or should be designed away. Strain relief boots should be sealed at the cable junction and tapered down to the cable diameter. Ball detents or securing methods must be designed to allow for ease of decontamination. Deep or small crevices increase the difficulty of reprocessing. Devices that are shaped like cups or have cup-like features should be avoided. Devices should be designed for reprocessing.
TUCKER RC, LESTINI BJ, and MARCHANT RE. Surface analysis of clinically used expanded PTFE endoscopic tubing treated by the STERIS process. *ASAIO J*, 1996, vol. 42, pp. 306–313.	The efficacy of the STERIS process to remove contamination from the inner surfaces of clinically used expanded polytetrafluoroethylene (PTFE) endoscope tubes treated with glutaraldehyde disinfectant solutions was studied. Samples of the flexible distal biopsy channel of colonoscope tubes were examined before and after a number of STERIS processing cycles by three techniques: Fourier transform infrared spectroscopy (FTIR), electron microscopy for chemical analysis (EMCA), and atomic force microscopy (AFM). Glutaraldehyde-fixed protein deposits identified on the tubing surface decreased with increased STERIS cycles. After twenty STERIS cycles, FTIR showed that ≈ 30 % of the contamination was removed. EMCA showed that 50 % of the contamination was removed. AFM showed variation between control and processed samples, including evidence of cracks in the residual contamination layer. Clinical glutaraldehyde treatment and subsequent device drying were suggested to be two major factors that limit effective cleaning of endoscopic tubing.
VERJAT D, PROGNON P, and DARBORD JC. Florescence-assay on traces of protein on reusable medical devices: cleaning efficiency. *Int J Pharm*, 1999, vol. 179, pp. 267–271.	Cleaning reusable medical devices before disinfection or sterilization is essential. Detection of residual proteins can be used to validate the process if a sensitive method is used. A fluorescent method (OPA bound to N,N dimethyl-2-mercapto-ethylammonium) was used to demonstrate the presence of amino acids on a medical device following cleaning. The sensitivity of that method (10-5 g/L) was assessed, and the applicability of that detection technique was verified, using three types of carriers (steel blades, glass tubes, ceramic penicylinders) and three types of contaminants (yeast extract, BSA with sheep blood, formaldehyde-fixed fibrin). The formaldehyde-fixed fibrin was the most resistant soil. Ceramic penicylinders and steel blades were easier to clean than glass tubes.
WHITBOURNE J, KUHNERT S, and MONNAT K. Validating the cleaning, disinfection, and sterilization of reusable medical devices. *Med Dev & Diag Ind*, June 1994, vol. 16, pp. 68–74.	Experience with validating cleaning, disinfection, and sterilization procedures for reusable medical instruments is described. FDA now mandates that reusable devices requiring cleaning, disinfection, or sterilization be designed to enable the necessary steps to be performed adequately. Manufacturers must establish and validate that devices can be reprocessed effectively after repeated use. Microorganisms bond or adhere strongly to many plastic and polymeric surfaces, and even vigorous cleaning may not reduce the bioburden significantly. Bioburden is removed from most metals easily.