



Révision

# Une proposition de système de classification de nettoyage pour les dispositifs médicaux réutilisables en complément de la classification de Spaulding

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## Résumé

L'application du système de classification de Spaulding pour l'utilisation sûre des dispositifs médicaux est un principe central de la prévention des infections. Initialement défini dans les années 1950, ce système définit les appareils et les surfaces comme étant critiques, semi-critiques ou non critiques selon la façon dont ils seront utilisés sur un patient. Différents niveaux de traitement antimicrobien, définis comme divers niveaux de désinfection ou de stérilisation, sont jugés appropriés pour réduire le risque d'infection chez le patient. Cependant, l'accent mis sur l'inactivation microbienne ne suffit pas à répondre à cette préoccupation, qui a été particulièrement mise en évidence dans les pratiques courantes des établissements de santé, soulignant l'importance sous-estimée du nettoyage et de l'atteinte de niveaux de propreté acceptables. Une compréhension plus approfondie de la microbiologie a évolué depuis les années 1950, ce qui a conduit à la réévaluation de la classification de Spaulding et à l'accent mis sur la réalisation d'un nettoyage approprié. Bien que sous-estimé, le nettoyage a toujours été important, car la présence de matières résiduelles sur les surfaces peut interférer avec l'efficacité du processus antimicrobien pour inactiver les micro-organismes, ainsi que d'autres risques

pour les patients, notamment les dommages aux dispositifs, les dysfonctionnements et les problèmes de biocompatibilité. Malheureusement, cela reste pertinent, comme en témoignent les rapports dans la littérature sur l'apparition d'infections et d'éclosions liées aux dispositifs en raison d'échecs dans le traitement des attentes. Cela s'explique, en partie, par la sophistication croissante des fonctionnalités et de la réutilisation de l'appareil, ainsi que par les instructions d'utilisation du fabricant. Par conséquent, il s'agit de la première description et recommandation d'un nouveau système de classification des nettoyages pour compléter l'utilisation des définitions traditionnelles de Spaulding afin d'aider à relever ces défis techniques modernes et les risques pour les patients. Ce système de classification quantitative basé sur les risques met en évidence le défi d'un nettoyage efficace basé sur la complexité des caractéristiques de l'appareil présent, en tant que variable isolée ayant un impact sur le nettoyage. Cette classification de nettoyage peut être utilisée en combinaison avec la classification de Spaulding pour améliorer la communication des risques de nettoyage d'un dispositif médical réutilisable entre les fabricants et les établissements de santé, et améliorer les pratiques de nettoyage établies. Ce nouveau système de classification des produits de nettoyage éclairera également la création future, la réflexion conceptuelle et les innovations correspondantes pour la réutilisation durable et sûre d'importants dispositifs médicaux.

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## Introduction

The safe use of any medical device always requires collaboration between the manufacturer and the healthcare user. For sterile, single-use medical devices, the product is provided ready for use; however, safety can only be assured when the device is handled correctly during storage and use at the healthcare facility. The requirement for this collaboration becomes even greater with medical devices intended to be processed prior to use or reuse by the healthcare facility. For reusable medical devices, greater responsibility for the mitigation of infection risk lies with the healthcare facility. This transfer of responsibility is communicated through manufacturer's instructions for use (IFU). As described in international standards, the medical device manufacturer must provide detailed processing instructions to ensure that, when followed correctly, the risk of patient infection or other complications is minimized [[1], [2], [3]]. The processing IFU are intended to standardize the quality of the medical device as appropriate to patient use. Product, including microbiological, quality is a qualitative concept that encompasses all activities which provide confidence that a medical device is safe for its intended use, and is more than just a consideration of the presence or absence of micro-organisms potentially remaining on a product. It includes residual chemicals or particulates which may remain on a device following use and processing that may also elicit an immune response in a patient [4].

Earle H. Spaulding defined a classification system to address the microbiological quality of medical devices processed within a healthcare facility in the 1950s [5]. This system needs to evolve in order to respond appropriately to the increasing complexity of reusable medical devices (e.g. endoscopes) since the late 1960s [5]. The Spaulding classification system for medical devices is based on the risk of transmission of infections [1]. This risk is based on the level of contact the device has with the patient. Devices are classified as critical, semi-critical or non-critical [6].

Critical devices include those that contact 'sterile' tissues (including blood and internal body spaces) during their use. Examples include surgical devices. It is recommended that these devices should be adequately cleaned, inspected and sterilized prior to patient use [1,5,7,8]. Semi-critical devices may only contact mucous membranes or non-intact skin. Examples include flexible colonoscopes, gastroscopes and respiratory equipment. It is also recommended that these devices should be adequately cleaned and sterilized prior to use. However, in many cases, they may be subjected to terminal high-level disinfection (HLD) instead of sterilization [1,5,7,8]. The purpose of HLD is to remove pathogens safely, but this may or may not include all dormant micro-organisms such as bacterial spores. Non-critical devices or instruments may contact intact skin but do not penetrate it. Examples include blood pressure cuffs, stethoscopes and skin electrodes (non-critical patient care devices). They also include a variety of equipment and environmental surfaces that may not contact the patient directly, but can become contaminated during use or over time in clinical practice (non-critical environmental surfaces). Recommended processing steps can include cleaning alone or cleaning with disinfection, where the level of disinfection can vary depending on the risk to patient or staff safety, as well as country-specific requirements [1,5,7,8].

The Spaulding classification focuses on the resistance of, and risks with, known micro-organisms (specifically pathogens) in parallel with the criticality of the device in clinical use. Although more information about microbial resistance profiles to inactivation is known today, this classification system, which focuses on use of disinfection and sterilization practices, is just as applicable today as it was when it was developed over 50 years ago [5]. However, criticism on the foundational resistance profiles of micro-organisms to inactivation has shown variability depending on the type of antimicrobial process being employed (especially with chemical disinfectants) [5]. It has been reported previously that exposure to implicit stresses can enable treated micro-organisms to adapt otherwise-lethal biocidal processes, particularly when embedded in complex biofilms [9]. Another topic of debate is the persistence of micro-organisms on environmental surfaces [10]. Despite being 'non-critical' surfaces, the transmission of micro-organisms from these surfaces to patients and staff has highlighted the importance of surface disinfection, particularly with bacterial spores (e.g. *Clostridioides difficile*), meticillin-resistant *Staphylococcus aureus* and, increasing problematic, Gram-negative bacteria (e.g.

*Pseudomonas aeruginosa*). In these situations, it is not necessary or practical to ensure that these surfaces are treated with sporicidal disinfectants/sterilants, but does emphasize the importance of physical removal (cleaning). Overall, these examples remind us to remain vigilant in our understanding of microbiology and the potential for unwanted microbial adaptation to frontline therapeutics and disinfection practices. It is rare that reports of failure of the Spaulding classification system have led to patient infections, when applied correctly. Unfortunately, it is more common that reports of device-associated infections and other patient complications with reusable devices/surfaces have arisen due to incorrect processing practices [7]. A review of the literature highlights common examples, such as inadequate device design or maintenance, poor water quality used at important stages of processing, use of inappropriate processing methods or antimicrobial technologies, and poor environmental controls during storage and handling of devices. Moreover, the most frequent reports appear to be related to failure of adequate cleaning, where a keyword search was completed using 'processing' and 'reusable medical device'. Of the 56 results, 18 were relevant (Table I). It should be noted that an important, yet underappreciated, consideration underpinning the earliest use of Spaulding's classification was that medical devices are clean prior to disinfection or sterilization. This assumption does not take into consideration the increasing number of different medical devices with highly complex device features that are not easy to clean, which reflects the dynamic and evolving needs of modern-day medicine.

Cleaning, defined as the removal of soil to the extent necessary for further processing or for intended use [11], is essential, and it has been demonstrated repeatedly in the literature that cleaning failures are a root cause of failing decontamination of reusable medical devices [5,12]. Many articles over the last 50 years have highlighted the need for more attention on the cleaning process related to medical devices with complex features, with increasing focus on the relationship between cleaning difficulty and hospital-acquired infections (HAIs) [13].

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## Section snippets

### How clean is safe?

At the time the Spaulding classification was widely adopted, the detailed measurement techniques or endpoints for determining cleanliness had yet to be established. Visual cleanliness was the expectation, and the Spaulding classification system was established with the foundational assumption that all devices would be visibly clean prior to the microbial reduction step of disinfection or sterilization. It was assumed that vigorous cleaning would always be performed, and, in many cases, devices

## Evaluation of risk

ISO 14971 describes the evaluation of risk as being a process of comparing an estimated risk against a risk criteria to determine the acceptability of that risk [52]. The hazardous situations at the healthcare facility leading to the inadequate processing of a reusable medical device can include human factors (e.g. inadequate training) leading to the inability to execute the required cleaning process [13], the time before or during the decontamination process that can lead to increased cleaning

## Cleaning classification

When the Spaulding classification was introduced, it provided a necessary framework for manufacturers, regulators and healthcare personnel to consistently deliver an appropriate microbiological reduction for devices. However, when using the Spaulding classification alone, the entirety of the microbiological quality of the reusable medical device is not considered, as the risk to ensure cleaning is not considered in detail. The introduction of a complementary cleaning classification system would

## Decontamination risk mitigation

Ineffective device processing is a major risk for HAIs and other patient complications. Complex features of devices can make visual inspection and monitoring for cleanliness difficult, thereby increasing the risk of soil accumulation and biofilm development. Medical device manufacturers can use this cleaning classification in conjunction with the Spaulding definitions to assess the risk for the entire decontamination process for reusable medical devices. This can improve cleaning and

## Conflict of interest statement

None declared.

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None.

Recommended articles

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