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Factors Influencing the Cleaning Quality of Reusable Medical Devices in a Chinese Healthcare Facility

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ABSTRACT

Inadequate cleaning is a major contributor to substandard sterilization and poses a significant risk for healthcare-associated infections. This study aimed to identify factors influencing the cleaning quality of reusable medical devices and propose measures to enhance their safe use and reduce iatrogenic infection risk. We conducted expert consultations to determine factors affecting the cleaning quality of reusable medical devices. Data were collected from the hospital's central sterile supply department (CSSD) between January and June 2022 using a self-developed inspection form evaluating cleaning quality. Additionally, cleaning staff's knowledge and perceptions regarding medical device cleaning were assessed through a self-designed questionnaire.

Significant associations ($P < 0.05$) were observed for incorrect cleaning procedures, inappropriate cleaning methods, non-standard pre-treatment, insufficient knowledge or misperceptions of device cleaning, and complex device structures. Independent factors linked to cleaning quality included adherence to correct cleaning procedures (odds ratio [OR] = 0.216, 95% confidence interval [CI]: 0.170–0.275), cleaning method selection (ultrasonic cleaning OR = 3.995, 95% CI: 2.937–5.434; spray cleaning OR = 0.893, 95% CI: 0.735–1.085), standard pre-treatment (OR = 1.470, 95% CI: 1.191–1.815), complex device structures (OR = 1.534, 95% CI: 1.247–1.888), and correct perceptions of cleaning among staff (OR = 0.530, 95% CI: 0.436–0.645). Improving the cleaning quality of reusable medical devices requires strict adherence to standardized procedures, appropriate cleaning method selection and pre-treatment, enhanced staff knowledge and awareness, and disassembly of complex devices to minimize cleaning defects.

Keywords: Cleaning quality, Reusable medical devices, Improvement measures, Factors

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Introduction

The central sterile supply department (CSSD) plays a vital role in hospitals by managing the cleaning, disinfection, and supply of sterile reusable medical devices, ensuring effective sterilization and minimizing the risk of hospital-acquired infections [1, 2]. These devices routinely come into contact with blood, bodily fluids, tissues, and excretions. Inadequate cleaning can leave organic matter that promotes biofilm formation [3, 4], allowing pathogens and viruses to persist on device surfaces. Complex structures such as shafts, joints, and grooves can further hinder thorough decontamination, making meticulous cleaning essential for successful sterilization [5, 6]. According to Dong *et al*. [7], the pass rate for cleaning reusable medical devices, assessed using adenosine triphosphate (ATP) bioluminescence, ranged from 80.1% to 94.6%. In their study, a desktop ATP fluorescence device (Ruhof Corporation, New York, USA) was used, with readings of ≤45 relative light units (RLUs) considered a pass. They tested 240 commonly used surgical devices, including rigid endoscopes, ophthalmological instruments, and powered tools (80 of each), using a single-blind on-site method before and after optimizing cleaning procedures. The number of devices passing the test increased from 194 to 227, confirming the reported range.

Gao *et al*. [8] reported that inadequate cleaning could reduce the success rate of autoclave sterilization to 70%–95%. In their study, sterilized instruments were sampled for microbial contamination, including pathogenic and non-pathogenic bacteria and spores, with items free of microorganisms deemed successfully sterilized. Poor cleaning is therefore a primary reason for inconsistent sterilization outcomes and a known contributor to nosocomial infections [9, 10].

These findings emphasize that cleaning is a critical step in reusable device processing, directly impacting sterilization quality. Identifying factors that affect cleaning performance is essential for improving device safety and preventing iatrogenic infections. This study investigates these factors and proposes measures to enhance cleaning quality.

Materials and Methods

Ethics approval

The study was conducted following the Declaration of Helsinki and relevant regulations. Ethical approval was granted by the Medical Ethics Committee of West China Second University Hospital, Sichuan University [2023 Medical Scientific Research for Ethical Approval No. (002)].

Study setting

From January to June 2022, 40,990 reusable medical devices were randomly selected by CSSD quality staff, with 512 devices identified as having cleaning failures. The study focused on common surgical instruments (scalpels, scissors, forceps, hemostats, needle holders, tissue forceps, retractors), endoscopic instruments (separating pliers, nondestructive forceps, pneumoperitoneum needles, grasping forceps, electrosurgical hooks, da Vinci robotic tools, rigid endoscopes), and precision instruments (ophthalmic, cardiovascular, oral, and nasal/facial plastic surgery tools). Devices rented from manufacturers, flexible bronchoscopes, gastrointestinal and urologic flexible endoscopes, and powered instruments were excluded. The hospital operates 45 surgical suites and performs roughly 60,000 surgeries annually, with the CSSD handling over 8 million reusable devices per year.

Study tools

Identification of factors affecting the cleaning quality of reusable medical devices

Based on a review of relevant literature [11, 12], the World Health Organization's Decontamination and Reprocessing of Medical Devices for Health-care Facilities [13], and the Central Sterile Supply Department (CSSD) – Part 2: Standard Operating Procedures for Cleaning, Disinfection, and Sterilization issued by the National Health Commission of China [14], potential factors influencing the cleaning quality of reusable medical devices were identified using root cause analysis and brainstorming. These factors were categorized as follows:

- Manpower: Includes insufficient staffing, low awareness of the importance of device cleaning, inadequate training, low educational levels, lack of accountability, and insufficient supervision by management personnel.
- Equipment: Encompasses shortages or malfunctioning of cleaning devices, and situations where water pressure or temperature does not meet required standards.
- Materials: Involves the use of inappropriate cleaning tools or agents, incorrect device quantity per cleaning batch, complex device structures, and residual cleaning agents or rust removers remaining on device surfaces after cleaning.
- Methods: Covers improper device classification, absence of cleaning flowcharts for special devices, failure to follow standard cleaning procedures, lack of pre-treatment, unsuitable cleaning techniques, incorrect disassembly, and improper loading into cleaning machines.
- Environment: Includes inadequate lighting, temperature, and humidity, insufficient workspace, noisy conditions, and risk of secondary contamination.

A consultation letter was drafted based on these factors and sent via email to six CSSD experts from different hospitals and provinces. All participants had at least 10 years of CSSD experience, extensive nursing management expertise, and were members of their respective provincial sterile supply committees. The panel comprised one chief nurse, two co-chief nurses, and three supervising nurses. Through consensus, the following key factors were confirmed as influencing cleaning quality:

1. Proper sorting of reusable medical devices prior to cleaning.

2. Use of correct cleaning procedures.
3. Choice of cleaning method.
4. Use of appropriate cleaning tools.
5. Implementation of pre-treatment steps.
6. Use of suitable cleaning agents.
7. Adequate knowledge of medical device cleaning among personnel.
8. Complexity of device structure.
9. Occurrence of secondary contamination.

Development of a cleaning quality inspection form

A specialized inspection form was developed to systematically capture information on: date and time of cleaning, device name, number and type of cleaning defects, device category, location of defects, performance of pre-treatment, cleaning method used, and associated factors contributing to cleaning defects. The form was completed using QR code scanning. Inspectors rigorously assessed the cleaning quality of all devices in the study, evaluated them against standardized criteria, and accurately recorded the information on the form in real time.

Evaluation criteria

Cleaning quality of reusable medical devices

Based on the Central Sterile Supply Department (CSSD) – Part 2: Standard Operating Procedures for Cleaning, Disinfection, and Sterilization issued by the National Health Commission of China [14] and supporting literature [15, 16], inspectors assessed cleaning quality through visual examination or using a light magnifier. A device was considered to have failed cleaning if any water stains, blood, dirt, or rust were observed on the surface, articulation points, grooves, or lumens.

Cleaning personnel's knowledge and perceptions

The knowledge and perceptions of CSSD cleaning personnel were evaluated using a self-developed questionnaire containing 10 items covering device names, disassembly methods, structure handling, cleaning steps, cleaning tools, and safety precautions. According to hospital assessment standards, the questionnaire was scored out of 100, with scores of 85 or higher indicating adequate knowledge and correct perceptions.

Cleaning procedures

Cleaning staff were required to follow the standard procedure sequence: flush → wash → rinse → terminal rinse.

Selection of cleaning tools

Lumen devices were cleaned using brushes appropriately sized for the lumen's length and diameter, while micro-fiber cloths were employed for precision device surfaces. Soft or hard brushes were chosen based on the device material, and abrasive tools were strictly prohibited.

Selection of cleaning agents

All devices were cleaned using agents from the same manufacturer and production batch to ensure consistency.

Data collection

Data on cleaning failures were collected using the cleaning quality inspection form. Additional information on the devices was retrieved from the hospital's information traceability system. Data entry was independently verified by two researchers. Each cleaning step for every device was supervised by the team's head nurse or quality controller, each with over 10 years of experience. All cleaning personnel, packaging staff, and quality controllers received training on relevant knowledge, procedures, and evaluation criteria to maintain accuracy, standardization, and minimize study deviations.

Statistical analysis

Data were analyzed using SPSS version 25.0. Categorical data are presented as [n (%)], and differences between groups were assessed using the Chi-square (χ^2) test. Variables showing significant differences between groups were treated as independent variables. Cleaning outcome (pass/fail) was used as the dependent variable and analyzed via multivariate logistic regression. Statistical significance was set at $\alpha = 0.05$ ($P < 0.05$).

Results and Discussion

Cleaning failures

Out of 40,990 devices sampled, 512 (1.25%) were classified as cleaning failures. Among these, 163 (31.8%) were common devices, 253 (49.4%) were endoscopic devices, and 96 (18.7%) were precision devices. The distribution and details of cleaning failure incidences across device types are illustrated in **Figures 1–3**.

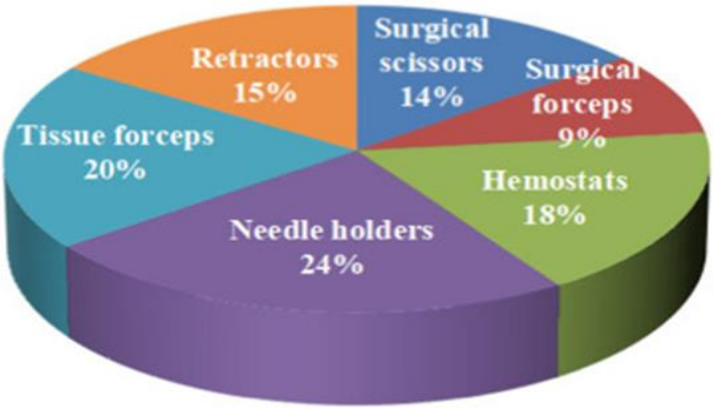

Figure 1. Frequency of Cleaning Failures in Common Devices

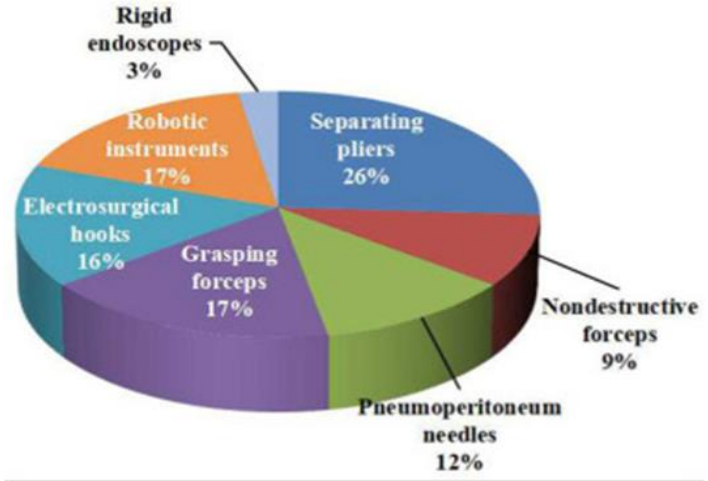

Figure 2. Frequency of Cleaning Failures in Endoscopic Devices

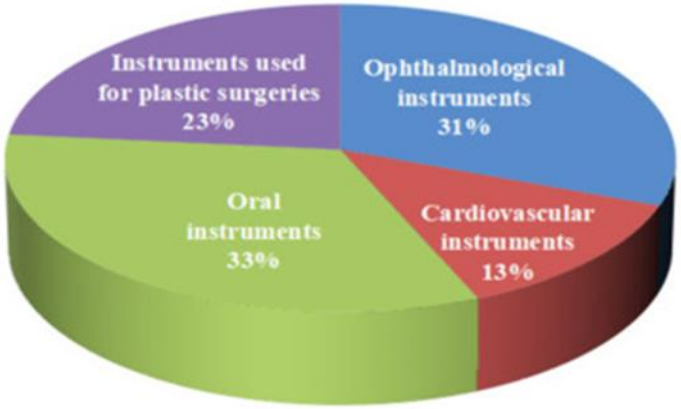

Figure 3. Frequency of Cleaning Failures in Precision Devices

Univariate analysis

Among the 40,990 devices, 512 (1.25%) were classified as cleaning failures, while 40,478 (98.75%) passed the cleaning assessment. Significant associations ($P < 0.05$) were observed for the following factors: whether the

device was properly sorted for cleaning, adherence to correct cleaning procedures, choice of cleaning method, use of appropriate cleaning tools, implementation of pre-treatment, cleaning personnel's knowledge of device cleaning, and the complexity of the device structure. No significant differences (P > 0.05) were found for the type of cleaning agents used or the occurrence of secondary contamination **(Table 1)**.

Table 1. Mono-factor analysis of the factors associated with the cleaning quality of reusable medical devices.

Variables	Grouping	Cleaning quality		χ^2	*P*
		Failure	Pass		
Was the reusable medical device properly sorted before cleaning?	Yes	278	24271		
	No	234	16207	6.753	0.009
Were the standard cleaning procedures correctly followed?	Yes	92	23848		
	No	420	16630	348.953	<0.001
What cleaning method was applied to the device?	Pulsating vacuum	49	14501		
	Ultrasonic cleaning	184	12446		
	Spray cleaning	279	13531	169.185	<0.001
Were appropriate cleaning tools utilized for the device?	Yes	230	16117		
	No	282	24361	5.496	0.019
Was pre-treatment carried out before cleaning the device?	Yes	121	7288		
	No	391	33190	10.185	0.001
Were appropriate cleaning agents used for the device?	Yes	383	29092		
	No	129	11386	2.154	0.142
Did the cleaning personnel have adequate knowledge of surgical instrument cleaning?	Yes	157	23295		
	No	355	17183	149.297	<0.001
Was the device's structure complex?	Yes	383	35829		
	No	129	4649	92.288	<0.001
Had any secondary contamination occurred?	Yes	342	25858		
	No	170	14629	1.863	0.172

Multivariate logistic regression analysis

The factors that showed statistically significant differences in the univariate analysis—including device sorting, adherence to correct cleaning procedures, cleaning method, use of appropriate tools, implementation of pre-treatment, cleaning personnel's knowledge of device cleaning, and device structural complexity—were included as independent variables in the multivariate logistic regression model. The dependent variable was the cleaning quality of the reusable medical devices. Detailed variable information is presented in **Table 2**.

Devices cleaned following the correct procedures had a significantly lower likelihood of failure (odds ratio [OR] = 0.216; 95% confidence interval [CI]: 0.170–0.275) compared with those cleaned incorrectly. Devices cleaned using ultrasonic cleaning showed a higher risk of failure (OR = 3.995; 95% CI: 2.937–5.434) than those cleaned with pulsating vacuum. The absence of pre-treatment increased the failure risk by 1.47 times (OR = 1.470; 95% CI: 1.191–1.815) compared with devices that underwent pre-treatment. Devices cleaned by personnel with adequate knowledge and proper understanding of medical device cleaning had a lower probability of failure (OR = 0.530; 95% CI: 0.436–0.645) than those cleaned by personnel with insufficient knowledge. Additionally, devices with complex structures were 1.534 times more likely to fail cleaning (OR = 1.534; 95% CI: 1.247–1.888) than those with simpler designs **(Table 3)**.

Table 2. Variable Assignments for Multivariate Analysis

Factor	Coding Description
Device sorted for cleaning	1 = Yes, 2 = No (reference group)

Correct cleaning procedures followed	1 = Yes, 2 = No (reference group)
Cleaning method applied	1 = Pulsating vacuum (reference group), 2 = Ultrasonic cleaning, 3 = Mechanical cleaning
Use of appropriate cleaning tools	1 = Yes, 2 = No (reference group)
Pre-treatment performed	1 = Yes, 2 = No (reference group)
Cleaning personnel's knowledge adequacy	1 = Yes, 2 = No (reference group)
Device structural complexity	1 = Yes, 2 = No (reference group)

Table 3. Multivariate Logistic Regression Analysis of Factors Affecting the Cleaning Quality of Reusable Medical Devices

Variable	Coefficient (B)	Standard Error	Wald χ^2	P-value	Odds Ratio (OR)	95% Confidence Interval (CI)
Device sorted for cleaning	0.214	0.162	1.745	0.187	1.239	0.902–1.702
Correct cleaning procedures used	−1.531	0.122	156.943	<0.001	0.216	0.170–0.275
Ultrasonic cleaning	1.385	0.157	77.912	<0.001	3.995	2.937–5.434
Spray cleaning	−0.113	0.099	1.295	0.255	0.893	0.735–1.085
Pre-treatment implemented	0.385	0.107	12.848	<0.001	1.470	1.191–1.815
Cleaning personnel knowledge adequate	−0.634	0.100	40.150	<0.001	0.530	0.436–0.645
Device structural complexity	0.428	0.106	16.334	<0.001	1.534	1.247–1.888
Constant	—	—	—	—	—	—

Influence of factors on reusable medical device cleaning quality

Table 4 summarizes the factors that either improve or compromise the cleaning quality of reusable medical devices.

Table 4. Impact of Factors on the Cleaning Quality of Reusable Medical Devices

Influencing Factor	Factors Favoring Cleaning Quality	Factors Detrimental to Cleaning Quality
Cleaning procedures	Adherence to correct procedures	Use of incorrect procedures
Cleaning methods	Pulsating vacuum cleaning	Ultrasonic cleaning
Pre-treatment	Properly implemented pre-treatment	Omission or improper pre-treatment
Cleaning personnel knowledge and perceptions	Adequate knowledge and correct perceptions	Inadequate knowledge or misconceptions
Device structure	Simple or uncomplex structure	Complex structure

With the continuous advancement of medical technology, the use and variety of medical devices in clinical practice have steadily increased, providing significant benefits to patient care. However, this growing diversity has also complicated the processes of disinfection, sterilization, and maintenance, placing greater demands on the work of the CSSD. Proper cleaning, disinfection, and sterilization of medical devices are critical for minimizing the risk of hospital-acquired infections [17]. Previous research by Li *et al*. [18] has indicated that cleaning quality is influenced by multiple factors, including inadequate pre-treatment, poor compliance with standard cleaning protocols, residues from cleaning agents, and insufficient instrument soaking time. Consistent with these findings, our study identified that deviations from correct cleaning procedures, inappropriate cleaning methods, non-standard pre-treatment, insufficient knowledge or misconceptions among cleaning personnel, and complex device structures were the primary contributors to cleaning failures, highlighting areas that require intervention for improved control.

Key influencing factors

Deviation from standard cleaning procedures: Cleaning staff do not always strictly adhere to established cleaning protocols. Steps may be skipped to save time or speed up processing, leading to suboptimal cleaning. In our study, such procedural lapses were the leading cause of cleaning failures, particularly during urgent processing of medical devices.

Choice of cleaning method: Although our analysis found no significant difference in cleaning quality between pulsating vacuum and spray cleaning, this may be due to the wide variety of devices used in the hospital, including lumen, precision, and common gynecologic devices. Each cleaning method is better suited to certain device types, and improper selection can obscure differences in cleaning effectiveness.

Non-standard pre-treatment: Previous work by Huang *et al*. [19] reported that only 57.24% of instruments received proper moistening before cleaning. Inadequate pre-treatment allows biofilm formation on devices within two hours of drying [20], which can later be removed using peracetic acid, alkaline or enzymatic cleaners, or glutaraldehyde [21]. Our findings show that non-standard or absent pre-treatment significantly impacts cleaning quality. In practice, heavy workloads and the high volume of medical procedures often prevent staff from properly pre-treating devices, allowing blood and other residues to dry on surfaces [22]. Attempts to remove these dried contaminants with abrasive tools can scratch the devices, promote rust, and compromise cleaning in subsequent uses. While some staff adhere to pre-treatment guidelines, lapses or lack of knowledge are common among clinical personnel.

Cleaning personnel's knowledge and perceptions: Subjective factors such as education level, attitudes toward cleaning, and understanding of job responsibilities can affect how cleaning is performed. Poor knowledge may result in incorrect preparation of cleaning agents, insufficient water pressure, inadequate soaking, or skipping critical steps, leading to unsatisfactory cleaning outcomes [23]. In our hospital, staff education levels ranged from junior to senior high school, and their work experience varied widely, which also contributed to differences in cleaning quality.

Complex device structure: Devices with intricate designs, narrow lumens, or multiple components are more prone to retain contaminants, compromising cleaning and sterilization. In our study, 253 of the 512 cleaning failures involved endoscopic devices, such as electrocoagulation forceps, cup-shaped uterus lifting devices, and endoscope irrigators, which feature long manipulators, grooves, and multiple parts. Blood and tissue residues are more likely to remain in these lumens, grooves, and articulation joints, making cleaning failures more frequent in complex devices compared to common devices.

Recommended prevention strategies

1. Adherence to Standard Cleaning Procedures: All medical devices should be cleaned strictly according to established standard procedures. These procedures, along with relevant guidelines, should be clearly communicated to CSSD personnel through a detailed cleaning workflow chart. A three-tier quality control system, including a head nurse, quality controllers, and inspectors, should be implemented to oversee compliance. The head nurse should perform random weekly inspections, quality controllers should conduct daily monitoring, and the cleaning team leader should supervise adherence to responsibilities, workflow, and management rules, ensuring devices are cleaned following the "flush – wash – rinse – terminal rinse" sequence. For devices requiring specialized cleaning, such as da Vinci robotic instruments, endoscopes, and precision devices, dedicated standard operating procedure (SOP) diagrams should be displayed at the cleaning stations for easy reference **(Figure 4)**. Additionally, to prevent skipping cleaning steps during urgent processing, hospitals should maintain an adequate supply of devices within budget constraints to reduce reliance on rapid cleaning under shortage conditions.
2. Appropriate Cleaning Methods for Device Types: Different device types should be cleaned using the most suitable method. For powered devices and precision ophthalmic instruments that require ultrasonic cleaning—where pulsating vacuum cleaning is unsuitable—it is recommended to first manually remove visible contaminants before ultrasonic cleaning, avoiding running water alone. For complex lumen devices, pulsating vacuum cleaning remains the preferred method [24].
3. Standardized Pre-treatment: Devices should be wiped clean of contaminants and sent to the CSSD within 30 minutes after use. If immediate cleaning is not possible, instruments must be kept moist by evenly spraying a moisturizing agent or immersing them completely. The CSSD should: (i) provide training and develop SOPs for pre-treatment in clinical departments, (ii) assign staff to guide instrument moistening,

and (iii) verify pre-treatment effectiveness upon collection. Ongoing training should continue until proper pre-treatment is consistently applied across all departments [25].

4. Enhancing Cleaning Personnel Knowledge and Perceptions: A cleaning "mind map" should be distributed to staff to reinforce understanding of procedures and facilitate skill development. Evaluation criteria for CSSD personnel should include theoretical knowledge, practical manipulation, integrative competence, and personal traits [26]. Training should cover the principles, workflow, and methods of cleaning, sorting techniques, handling of special instruments, choice of equipment, cleaning tools and agents, and proper operation of cleaning devices. Demonstrations, drills, and instructional videos are recommended to strengthen skills, safety awareness, and cleaning quality. Post-training assessments should be conducted, and performance-based incentives can motivate staff. Distinct technical and general roles are advised, with specialized positions for endoscopic, powered, and precision device cleaning, clearly defining responsibilities and ensuring familiarity with disassembly and cleaning procedures for each device type.
5. Disassembly of Complex Devices: Devices with intricate structures should be disassembled prior to cleaning. Detailed disassembly workflow charts should be created, highlighting key components and displayed at the cleaning stations for reference. Components such as shafts, screws, cores, and manipulators should be cleaned individually following manual procedures. If disassembly is not possible, devices should be left in an open (unlocked) position before applying ultrasonic or pulsating vacuum cleaning.

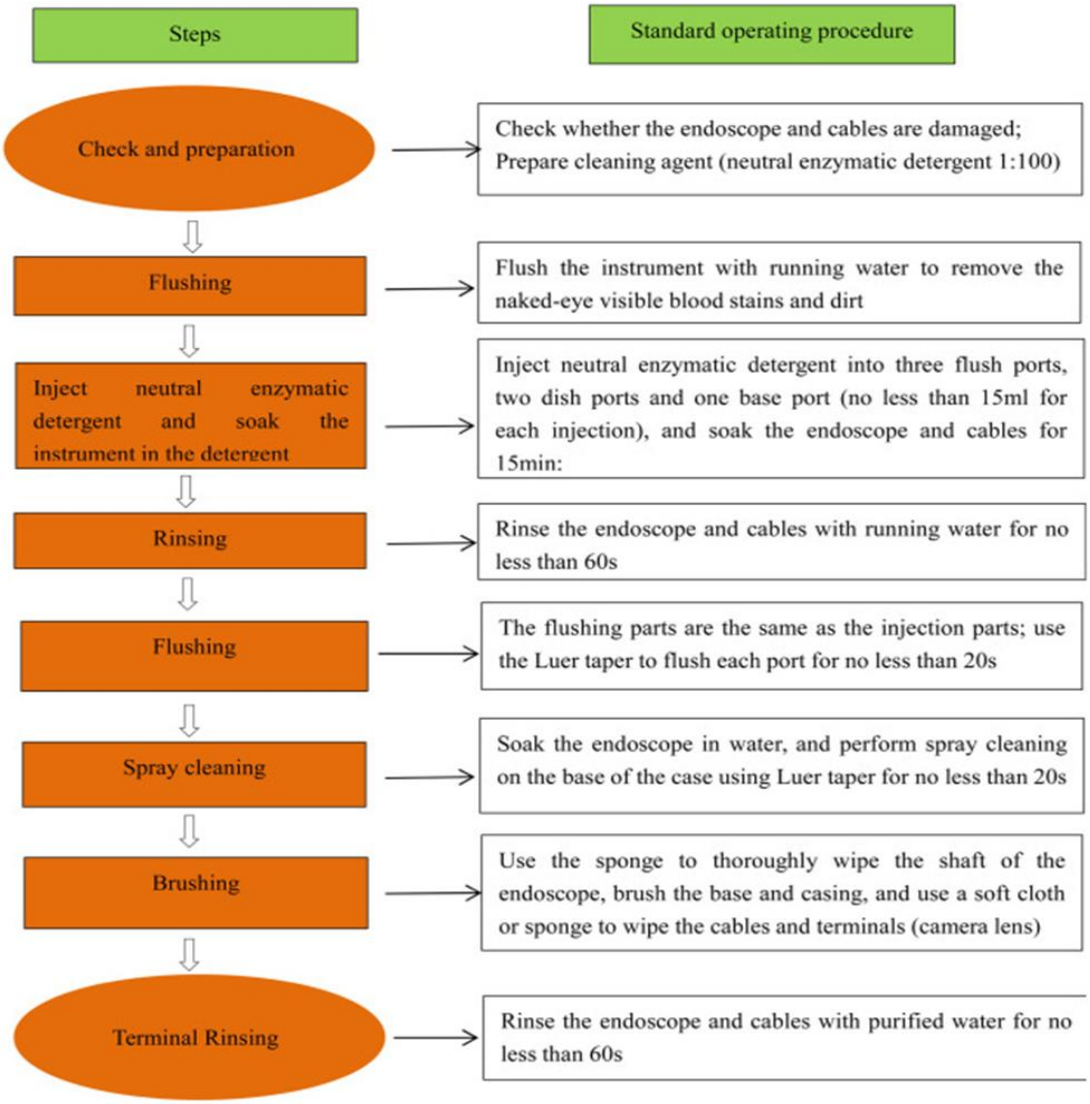

Figure 4. Standard workflow for cleaning the da Vinci robotic endoscope.

Conclusion

Enhancing the cleaning quality of reusable medical devices requires strict adherence to standard cleaning protocols, appropriate selection of cleaning methods and pre-treatment, strengthening cleaning personnel's knowledge and understanding of device cleaning, and proper disassembly of devices with complex structures to minimize cleaning defects. The range of cleaning methods assessed in this study was limited; future investigations could explore additional approaches, such as spray cleaning or reduced-pressure boiling, to evaluate their effectiveness. Furthermore, this study assessed cleaning quality through visual inspection and light magnification rather than quantitative measurements. Subsequent research may incorporate more objective evaluation techniques, such as protein residue analysis or ATP fluorescence testing, to more accurately assess cleaning outcomes.

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Conflict of Interest: None

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Ethics Statement: This study was reviewed and approved by the Medical Ethics Committee of West China Second University Hospital, Sichuan University, with the approval number: 2023 Medical Scientific Research for Ethical Approval No. (002). All participants provided informed consent to participate in the study.

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