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# Advances in Cleaning Technologies for Luminal Medical Devices

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**ABSTRACT:** Luminal instruments, with their complex configurations, narrow lumens, and tendency to retain organic matter after use, are the most difficult category to clean in the Central Sterile Supply Department (CSSD) and have the highest re-cleaning rates. Their cleaning quality directly affects sterilization outcomes and patient safety. However, current technologies still face several persistent challenges: the absence of standardized pre-treatment protocols, marked variability in the efficacy of different moisturizing methods, and biofilm formation resulting from extended holding times of contaminated instruments; manual cleaning that depends heavily on operator technique, leading to inconsistent results; insufficient adaptability of mechanical cleaning equipment to complex luminal geometries, with steam penetration constrained by lumen length and diameter; and quality assessment that still relies primarily on visual inspection, while quantitative methods remain underutilized, making it difficult to accurately evaluate cleaning efficacy inside lumens. This article systematically reviews research progress on luminal instrument cleaning technologies in China from four perspectives: pre-treatment techniques, improvements in cleaning tools, upgrades to mechanical cleaning equipment, and quality assessment methods. For pre-treatment, this article evaluates the efficacy and operational convenience of various moisturizing agents and pre-cleaning approaches for biofilm disruption/loosening. For cleaning tools, this article describes the design rationale and clinical benefits of novel luminal cleaning racks, fixation devices, and internal illumination systems. For mechanical cleaning, this article details the operating principles and efficiency gains of pulsating vacuum washer-disinfectors and ultrasonic cleaning equipment. For quality assessment, this article compares the sensitivity and applicable contexts of visual inspection, Adenosine Triphosphate (ATP) bioluminescence assay, and protein residue detection. By examining the strengths and limitations of each technology, this article identifies current trends and suggests future research directions, with the aim of offering practical guidance for cleaning quality management of luminal instruments and informing subsequent investigations.

**KEY WORDS:** Luminal instrument; Cleaning technology; Pre-treatment; Mechanical cleaning; Quality check

Luminal instruments are defined as medical devices featuring a luminal structure with an internal diameter of no less than 2 mm, in which the distance from any point inside the lumen to the nearest external opening does not exceed 1 500 times the internal diameter[1]. Such devices, encompassing a broad array of types, including suction tips, puncture frames, rigid endoscopes, robotic surgical instruments, silicone irrigation tubing, cannulated screws, and intramedullary nails[2], are commonly employed in puncture drainage, fluid aspiration, endoscopic diagnosis and treatment, and intraoperative implantation. Their long, narrow lumens, some of which are additionally equipped with lateral holes or curved designs, render the inner walls highly susceptible to contamination by organic residues (e. g., blood and tissue fluid) following use, thereby posing substantial obstacles to effective cleaning[3-4]. In terms of cleaning equipment, a unified cleaning rack that can accommodate luminal instruments of diverse specifications and

enable centralized processing is not yet commercially available, making continued dependence on manual cleaning methods necessary[5]. Conventional manual cleaning regimens generally rely on multi-enzyme detergent immersion, ultrasonic oscillation, and subsequent brushing with appropriately sized brushes, a process that suffers from low throughput and limited efficiency[6]. Consequently, luminal instruments continue to be classified among the most challenging devices to clean within the CSSD and exhibit the highest rates of re-processing[7-8]. Furthermore, deviations from prescribed cleaning protocols may result in incomplete contaminant removal, which can compromise sterilization performance[9]. Notably, bacterial biofilms that develop on moist luminal surfaces can significantly hinder the penetration of sterilizing agents, leading to sterilization failure and constituting a significant latent risk for healthcare-associated infection (HAI) [10-11]. Hence, guaranteeing the thorough cleaning of luminal instruments remains a critical focus and a persistent difficulty in CSSD quality assurance.

## 1 Cleaning and Disinfection Process

### 1.1 Pre-treatment

Pre-treatment is a critical step between instrument use and formal cleaning; its primary objectives are to prevent contaminant drying and reduce the difficulty of subsequent cleaning, thus serving as a prerequisite for ensuring cleaning quality. In many Chinese hospitals, the absence of a 24-hour CSSD service means that luminal instruments are often not processed immediately after use, which may compromise their later reprocessing. Consequently, proper pre-treatment of these instruments is of particular importance[12].

Common pre-treatment agents used in clinical practice include alkaline cleaners, multi-enzyme detergents, moisturizing gels, and foam-based moisturizing agents[13]. Among these, multi-enzyme detergent has traditionally been the mainstream choice; however, its clinical application is constrained by several limitations. The enzymatic activity of diluted multi-enzyme solutions gradually declines over time and typically becomes completely ineffective within 4 hours. Moreover, the optimal temperature for enzymatic activity is 40℃, which is challenging to maintain under routine clinical conditions, thereby limiting the efficacy of its enzymatic decontamination properties[14]. Foam-type multi-enzyme pre-treatment agents represent a significant advancement in luminal instrument pre-treatment technology. This product physically activates a multi-enzyme concentrate via a foaming device, generating a dense foam that is sprayed onto the instrument surface. It offers three core advantages over traditional pre-treatment agents: (1) It requires no dilution, allowing direct application and ensuring that enzymatic activity is preserved from the outset; (2) the foam exhibits low surface tension, enabling sustained coverage of the instrument surface for up to 24 hours, effectively isolating air and preventing contaminant oxidation and drying; and (3) it contains a five-enzyme system capable of rapidly and efficiently degrading various organic substances, including blood and tissue fluids[15]. SHI et al.[16] compared the pre-treatment efficacy of foam-type moisturizing agent versus traditional multi-enzyme soaking for gynecological suction instruments, and found that the foam-type agent was significantly more effective in removing proteinaceous organic matter. The timing of instrument cleaning and its coordination with moisturizing methods critically influence pre-treatment outcomes. Instruments left overnight without effective moisturizing are prone to contaminant drying, which directly leads to a marked decline in cleaning acceptance rates. Relevant studies have shown that for luminal instruments left overnight for 8 hours without moisturizing pre-treatment, the cleaning acceptance rate assessed by visual inspection was only 86.0%, and the Adenosine Triphosphate (ATP) bioluminescence assay qualification rate was only 67.0%[17]. LI et al.[17] further investigated the interactive effects of processing timing and moisturizing methods on luminal instrument cleaning quality, and drew three key conclusions: (1) Regardless of whether cleaning is performed immediately, the use of foam-type moisturizing agents significantly improves cleaning accep-

tance rates; (2) even when moisturizing agents are used, timely cleaning remains substantially more effective than delayed cleaning; and (3) for instruments that cannot be promptly cleaned in clinical practice, foam moisturizing agents can effectively improve ATP assay qualification rates, demonstrating considerable clinical utility.

Overall, the core principles of luminal instrument pre-treatment are to select suitable moisturizing agents and standardize cleaning procedures according to the specific structural features of the instruments and the major cleaning challenges, while minimizing the holding time before formal cleaning to prevent contaminant drying within the lumens, thereby reducing the difficulty of subsequent cleaning at the source.

1.2 Cleaning

Cleaning constitutes the central step in luminal instrument reprocessing and is performed via two principal modalities: manual cleaning and mechanical cleaning. The synergistic optimization and integration of these modalities are essential for enhancing both cleaning quality and operational efficiency. Manual cleaning remains the foundational approach for processing delicate and geometrically complex luminal instruments, and the effectiveness of manual cleaning is largely governed by the selection and usage of appropriate cleaning brushes. Mechanical cleaning, in turn, enables standardized and high-throughput processing, and the development of specialized cleaning equipment and supportive accessories constitutes a primary strategic direction in this domain. Current investigations are directed toward optimizing the overall cleaning and disinfection workflow through technical improvements and innovations in mechanized auxiliary devices, with the objectives of increasing cleaning acceptance rates, preserving instrument integrity, and prolonging instrument service life[6].

1.2.1 Cleaning tools

Traditional cleaning brushes for luminal instruments are composed of a metal wire core covered with nylon bristles. When used for brushing, the bristles contact the inner lumen wall only at discrete points, resulting in blind spots and incomplete cleaning. Furthermore, the bristles are prone to wear and distortion, leading to a gradual decline in cleaning performance with extended use. The mechanical friction exerted by such brushes is also insufficient to dislodge tenacious contaminants adhering to the inner lumen surface, rendering thorough removal difficult[7]. In response to these limitations, Chinese researchers have carried out a series of tool modifications[18-21]. The results confirm that the modified cleaning tools significantly improve both the cleaning quality of luminal instruments and the efficiency of the cleaning process, thus offering improved solutions for clinical manual cleaning operations.

Traditional fully automatic washer-disinfectors primarily use spray-arm rinsing for cleaning; however, the water flow exerts limited force on the inner lumen walls, making thorough cleaning of the luminal interior difficult. To address this issue, researchers have developed various specialized cleaning racks for luminal instruments[2,5,22]. These racks direct water flow directly onto the inner lumen walls via dedicated connectors, thereby enhancing cleaning effectiveness within the lumens and improving both the batch processing capability and standardization of mechanical cleaning. In the realm of specialized cleaning equipment, the introduction of vacuum ultrasonic cleaning machines and vacuum boiling cleaning machines constitutes a significant advance in mechanical cleaning technology for luminal instruments. Vacuum ultrasonic cleaning machines combine the benefits of vacuum technology with ultrasonic cleaning. Under vacuum conditions, air trapped within the lumens is evacuated, allowing the cleaning solution to completely fill the luminal spaces and enabling the ultrasonic cavitation effect to be fully utilized. ZHANG et al.[11] confirmed that vacuum ultrasonic cleaning combined with anti-biofilm cleaning agents produces a marked synergistic decontamination effect. Vacuum boiling cleaning operates by generating vapor-phase pulses through pressure differentials. Under vacuum, the boiling point of the cleaning solution is lowered to approximately 50℃; the scouring action of bubbles generated during

boiling cleans the instrument surfaces, while the liquid-to-vapor phase transition within the lumens forces the cleaning solution out of the luminal interior. When pressure is restored, water re-enters the luminal spaces, achieving deep cleaning[23]. The vacuum boiling cleaning machine is straightforward to operate, does not require dedicated loading racks for luminal fixation, and permits mixed loading of instruments, which improves work efficiency while eliminating the risk of instrument damage associated with high-frequency oscillation[24].

1.2.2 Integrated cleaning strategies

Each individual cleaning method possesses distinct advantages and limitations. The organic integration of manual cleaning with various mechanical cleaning modalities into a combined cleaning strategy has become an important direction in the evolution of luminal instrument cleaning. For lumens with complex geometries and for stubborn contaminants, rigorous manual cleaning remains indispensable for achieving complete soil removal. The procedure begins with an initial rinse under running water, followed by immersion in a multi-enzyme cleaning solution for 3 to 5 minutes. While immersed, the external surfaces are wiped unidirectionally with a low-lint cloth. Subsequently, a brush of suitable diameter and length is passed through the entire lumen, ensuring that the bristles maintain full contact with the inner walls, and is advanced with a 360° reciprocating motion in a consistent direction until it emerges from the opposite end. Both the cloth and the brush are disinfected immediately after use to avoid serving as potential vectors of cross-infection.

Building on manual cleaning, researchers have adopted various supplementary techniques to further improve the cleanliness of luminal instrument interiors. For instance, the use of steam spray guns during cleaning enables high-temperature steam to directly penetrate instrument gaps and lumens, thereby dissolving or dislodging concealed contaminants and achieving satisfactory cleaning outcomes[25]. In addition, following enzyme-solution brushing, dual-frequency ultrasonic cleaning is employed to enhance the cavitation effect, which reduces cleaning blind spots and ensures effective cleaning of luminal instruments[26]. It should be noted, however, that the decision to subject precision luminal instruments to ultrasonic cleaning must be guided by the manufacturer's instructions for use. ZHANG et al.[27], drawing on the best available evidence, developed a cleaning protocol for metal luminal suction instruments that integrates a multi-step approach: timely foam-based moisturizing pre-treatment, ultrasonication followed by manual through-brushing, and mechanical cleaning using dedicated cleaning racks. The study also emphasized that sustained improvement in luminal instrument cleaning quality depends on concurrent advances in both technical innovation and management optimization, as neither aspect can be overlooked.

1.3 Rinsing

Rinsing is an important step in the instrument cleaning workflow. It involves the use of large volumes of running water to thoroughly remove enzyme solutions from both the external surfaces and the luminal interiors of instruments. During this procedure, the pressure water gun should be kept below the liquid surface to allow repeated flushing of the lumens, with each rinse lasting at least 30 seconds, until no cleaning agent residue is detectable either inside or outside the lumens. The quality of water used for the final rinse is a critical determinant of overall cleaning effectiveness[6]. Inadequate rinsing or incomplete removal of enzyme residues may predispose luminal instruments to biofilm formation. Furthermore, elevated concentrations of calcium and magnesium ions in purified water can lead to the formation of white deposits on instrument surfaces, potentially shortening their service life. Filter membranes in water treatment systems require periodic replacement to prevent bacterial, viral, and other microbial contamination resulting from diminished filtration efficiency. After the final rinse, the cleanliness of the luminal interior should still be verified; if any contaminant residue remains, the instrument should be re-brushed.

1.4 Disinfection

For heat- and moisture-tolerant luminal instruments, mechanical thermal disinfection is the pre-

ferred method following manual cleaning. The instruments are placed in a boiling water disinfector, fully submerged and positioned at least 2 cm below the water surface, with the lumens completely filled with water, and disinfected by boiling with the lid closed. For heat-sensitive luminal instruments, alternative methods include immersion in 75% ethanol solution for 30 minutes or longer (with the container covered), or in 500 mg/L chlorine-containing disinfectant for more than 10 minutes. The specific disinfection method should be selected in accordance with the Chinese health industry standard *Regulation of disinfection technique in healthcare settings* (WS/T 367—2012).

1.5 Drying

Drying is an essential step in luminal instrument reprocessing. Insufficient drying may lead to internal rusting of the lumens, biofilm formation, and even HAI[28-29]. The use of dedicated drying equipment is recommended, with temperatures set at 70~90℃ for metal instruments and 65~75℃ for plastic ones[1]. At present, pressure air guns combined with conventional drying devices remain the standard practice in most CSSDs; however, this approach often fails to ensure complete drying for luminal instruments with blind-end configurations, posing potential safety risks[6]. Low-temperature vacuum drying, which operates under negative pressure, removes residual moisture from lumens by suction. This technique offers the advantages of short processing time, low energy consumption, and high efficiency, although its widespread adoption is limited by high equipment acquisition and maintenance costs.

## 2 Cleaning Quality Monitoring

2.1 Monitoring methods

In clinical practice, visual inspection is routinely used to assess the apparent cleanliness of luminal instruments following cleaning and disinfection. For evaluating the cleanliness of luminal interiors, the white gauze swab method or the white probe method is commonly employed; the choice of method may be guided by the structural features of the instrument in question[30]. However, visual inspection is subject to variability arising from the examiner's visual acuity, ambient lighting conditions, and other factors. These limitations are particularly pronounced for luminal instruments, making objective assessment of internal cleaning efficacy difficult[31]. Moreover, visual inspection can only detect contaminants larger than 50 μg on exposed or superficial surfaces, while dispersed, fine, or intraluminal residues are often not identifiable[32]. With advances in artificial intelligence and related technologies, digital and scientifically validated approaches have effectively compensated for the subjective biases inherent in human-dependent visual inspection. For example, the ATP assay offers rapid detection, simple operation, and quantifiable results, and has thus been widely adopted in the field of instrument cleaning quality assessment[33]. Studies have demonstrated that ATP assay can effectively detect trace contamination that is invisible to the naked eye, representing a sensitive means of evaluating the cleanliness of inner lumen walls[34]. Residual protein detection, which measures protein residues on both the luminal and external surfaces of medical devices, provides highly accurate results and enables reliable evaluation of cleaning efficacy[35]. The qualification rates obtained by protein residue testing have been shown to correlate well with ATP assay results[11]. Notably, substantial differences in sensitivity exist among different protein detection methods: the 3M Clean-Trace Hygiene Management System, based on the luciferase/luciferin bioluminescence reaction, has a sensitivity of 50 μg, whereas the One Life Detect kit, based on the Coomassie Brilliant Blue staining mechanism, has a sensitivity of 75 μg/cm$^2$[36]. In a cleaning verification study of da Vinci XI Robotic Surgical System, Sagourin et al.[36] suggested that routine process monitoring may underestimate the actual contamination level of structurally complex semi-blind-end luminal instruments, necessitating the use of destructive testing or the combination of multiple complementary methods. The borescope, or lumen inspection device, has emerged in recent years as a valuable visualization tool for luminal instrument cleaning quality assessment. Equipped with an ultra-

fine high-definition camera and an LED light source, it can be inserted directly into the lumen to transmit real-time images of the inner wall to an external display, thereby enabling direct visualization of luminal cleanliness. This device can effectively identify trace residues and rust spots that are undetectable by conventional visual inspection or the white gauze probe methods, and is particularly well suited for cleaning-challenging luminal instruments, such as those made of copper or those with narrow diameters[37].

2.2 Multi-dimensional monitoring system

Comprehensively, existing research and recommendations from international guidelines indicate that no single monitoring method can provide a comprehensive or accurate assessment of cleaning and disinfection quality for luminal instruments. The American standard *Cleaning Validation Of Health Care Products - Requirements For Development And Validation Of A Cleaning Process For Medical Devices* (AAMI ST98: 2022) explicitly mandates that cleaning validation employ a multi-method strategy incorporating visual inspection, chemical indicators, and quantitative testing[38]. In line with this, authoritative guidelines and expert consensus recommend the establishment of a hierarchical, multidimensional monitoring system for luminal instruments[39], structured at three levels: (1) Routine monitoring: visual or magnified inspection as the primary approach, supplemented by white gauze and white probe methods to enable rapid initial screening. Ambient illuminance should be maintained at ⩾500 lux, and 3–5× magnifying lenses should be used when necessary. (2) Periodic monitoring: quantitative sampling using ATP assay or protein residue detection, recommended at least once per week, with different categories of luminal instruments covered in each session, to allow timely assessment of overall cleaning quality. Institutional RLU thresholds for ATP assay should be established and regularly calibrated. (3) Special assessment: when new instruments are introduced, new cleaning procedures are implemented, or suspected infection outbreaks occur, borescope visualization or destructive protein residue testing should be employed to precisely identify cleaning deficiencies and analyze their root causes.

## 3 Conclusion and Perspectives

Cleaning equipment and tools for luminal instruments in China continue to expand in variety. Nevertheless, the structural complexity and material diversity of these devices mean that current cleaning technologies still fall short of overcoming the core challenges inherent in their cleaning. Inadequate cleaning that results in sterilization failure continues to constitute a significant risk factor for HAI. Consequently, improving the cleaning quality of luminal instruments remains a long-standing priority in clinical infection control. In clinical practice, efforts to enhance cleaning quality should be directed toward the following core aspects: implementing standardized pre-treatment protocols to effectively reduce the holding time of contaminated instruments and inhibit biofilm formation; adopting integrated cleaning strategies that combine manual and mechanical approaches; strictly adhering to industry-standard operating procedures to ensure thorough drying and guarantee satisfactory disinfection outcomes; and establishing a multi-tiered, multidimensional monitoring system that incorporates visual inspection, quantitative assays, and visualization tools for systematic evaluation. In addition, regular training and competency assessment of CSSD personnel must be reinforced, along with comprehensive, systematic quality monitoring and control, so as to minimize the risk of HAI and safeguard patient safety.

High-quality studies, both domestic and international, indicate six key trends in luminal instrument cleaning: refined pre-treatment, tool customization, equipment specialization, detection diversification, process integration, and intelligent management. In light of existing technological limitations and clinical requirements, future work in this field might focus on the following priorities: (1) Conducting multicenter, large-sample randomized controlled trials to further validate the clinical generalizability of various cleaning techniques, thereby providing Level 1 evidence to support their broader adoption; (2) developing evidence-based predictive models for cleaning

efficacy by incorporating variables such as instrument material, type of contamination, lumen geometry, and time elapsed before cleaning, to establish a risk-scoring system that can inform individualized cleaning protocols; (3) promoting the clinical translation and application of intelligent cleaning equipment through strengthened collaboration between engineers and clinicians, with the aim of developing systems capable of automatic parameter matching, real-time quality monitoring during cleaning, and automatic abnormality alerting, thus enhancing both standardization and intelligence in cleaning operations; (4) developing efficient, low-irritation anti-biofilm cleaning agents; and (5) establishing a decision-making pathway for the selection of luminal instrument cleaning technologies, based on instrument structural characteristics, contamination levels, and institutional resource availability, so as to provide actionable and context-appropriate technical guidance for healthcare facilities at different levels.

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