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Research on the Entire Process Parameter Validation and Quality Control System for Sterilization of Special Luminal Devices Based on Risk Assessment

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Abstract: *Objective*: To compare the temperature and time characteristics of specialized lumen instruments versus standard dressing test kits throughout the pre-vacuum pressure steam sterilization process, and to identify major risks during sterilization and drying stages. *Methods*: Three sterilizers from two campuses of a tertiary hospital were selected, using non-metallic lumens, metallic endoscope lumens, and a 7 kg standard dressing test kit as subjects. Miniature probes were placed inside the lumens or at the center of the test kits, with parameters for the initial pulse phase, heating phase, sterilization maintenance phase, and drying phase recorded under maximum challenging loading conditions. *Results*: During the initial pulse phase, the heating rates of standard test kits across all three devices were slower than those of lumen instruments. After entering the heating and sterilization maintenance phases, all load parameters converged, with most measurement points recording sterilization temperatures between 134.6–135.4 ℃ and exposure times meeting specified requirements. Significant differences in drying performance were observed among brands: Brand C exhibited the shortest average drying time (1286 s), while Non-Metallic Lumen 1 showed the highest average temperature (92.9 ℃), indicating that localized high temperatures do not necessarily equate to adequate drying, and wet-dress risk may be associated with insufficient removal of residual steam or condensation. *Conclusion*: Under the loading conditions and sterilization protocols studied, specialized lumen instruments did not demonstrate higher sterilization failure risks compared to standard dressing kits; when standard dressing test kits met sterilization parameters, lumen instruments typically also satisfied required sterilization temperatures and durations. Quality control should shift from solely focusing on compliance to balancing sterilization and drying processes, with particular emphasis on optimizing loading management for non-metallic lumens, refining drying procedures, and enhancing tracking of wet-dress conditions.

Keywords: Special luminal instruments; Pressure steam sterilization; Process validation device (PCD); Wet pack; Temperature and pressure validation; Quality control system.

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1. Introduction

Pressure steam sterilization offers advantages such as strong penetration capability, process monitorability, and cost controllability, making it the preferred final sterilization method for medical devices resistant to moist heat. Its efficacy depends on adequate contact between saturated steam and the device surface within a specified time frame, coupled with the release of latent heat; thus, factors including air removal, steam quality, loading and packaging conditions, temperature, pressure, exposure duration, and drying effectiveness all influence sterility assurance. With advancements in minimally invasive and robot-assisted surgeries, reusable devices exhibit characteristics such as slender luminal profiles, complex structures, and diverse materials, where residual air retention, localized cold spots, and inadequate condensate drainage may pose significant challenges. Relying solely on chamber display parameters or external chemical monitoring fails to accurately reflect the true sterilization status of the most difficult-to-sterilize areas of devices [1].

WS 310.3–2016 mandates the monitoring of critical parameters such as temperature, pressure, and duration for steam sterilization under pressure, with retention of quality control and traceability records; corresponding validation shall be performed upon new installation, relocation, major overhaul, or changes in process conditions [2]. ISO 17665 emphasizes the development, validation, and routine control of moist heat sterilization processes, while AAMI ST79 provides systematic recommendations covering equipment, loading, packaging, monitoring, and continuous improvement [3,4]. Therefore, quality assurance for complex medical devices should be based on a combination of risk assessment, physical parameter validation, and chemical and biological monitoring.

Moisture retention is another critical risk in pressure steam sterilization. Residual moisture within packaging or lumens can compromise the sterility barrier, leading to rework, increased equipment workload, and delayed instrument turnover. Flexible non-metallic long-lumen devices are particularly prone to condensation accumulation due to variations in thermal conductivity, structural design, and drainage pathways. Previous studies have primarily focused on the applicability of PCD or sterilization efficacy for individual devices, while comparative data regarding multi-brand devices, comprehensive process parameters across different material lumens, and drying risks remain limited [5,6]. Guided by risk assessment principles, this study deployed micro-probes at the most challenging sterilization sites under maximum loading conditions to compare sterilization and drying processes between specialized lumen devices and standard test packages, thereby providing evidence for developing targeted end-to-end quality control strategies.

2. Materials and methods

2.1. Study subjects

Equipment: Three representative pre-vacuum pressure steam sterilizers from different brands were selected from two campuses of a tertiary hospital, namely Brand A (Beiliman, model:), Brand B (Shidirui, model:), and Brand C (Jieding, model:).

apparatus :

Sterilization Process Testing Group: Cavity-based instruments with a length> 30 cm.

Control group: 7 kg standard dressing test kit prepared in accordance with the requirements of GB8599-2023.

Wet Bag Study Group: Surgical skin tubing, suction and irrigation tubing (length: 100–200 cm).

The physical appearance of these representative devices is shown in **Figure 1**, and their specific lumen characteristics are summarized in **Table 1**.

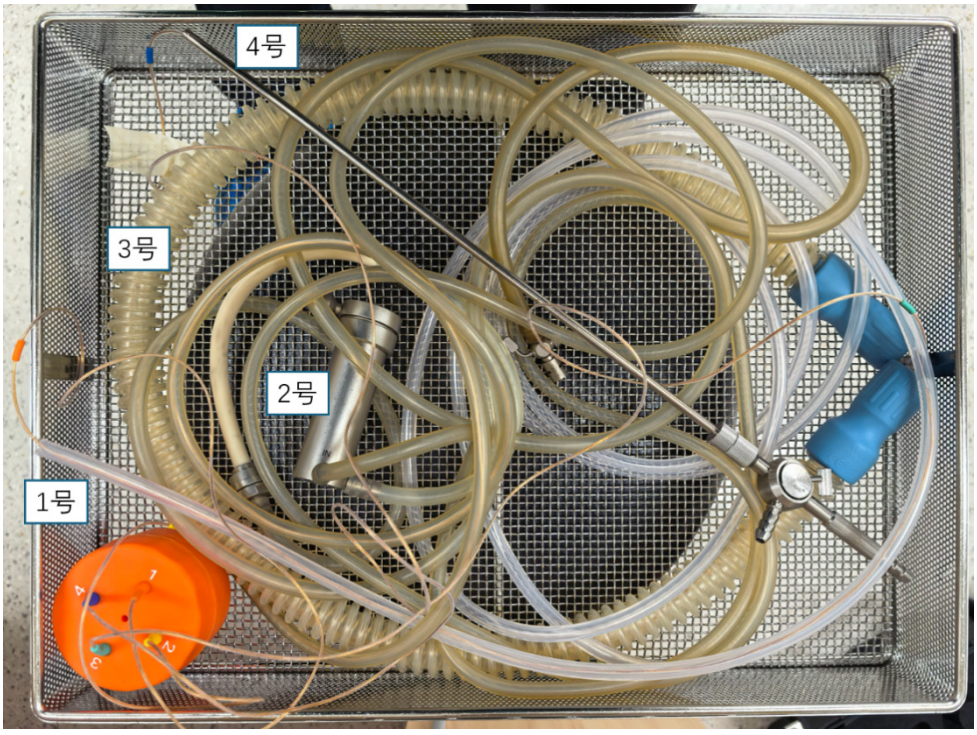

Figure 1. Representative physical images of the test group devices.

Table 1. Summary of lumen characteristics for various types in the test group

Device code	Device name	Material of the device	Lumen diameter	Lumen length
No.1 non-metallic lumen 1#	Hysteroscopic cannula	Medical silicone	6.4 mm	160 cm
No.2 non-metallic lumen 2#	Urological Irrigation Pump	Polystyrene	8.5 mm	178 cm
No.3 coarse non-metallic lumen	Ventilator tubing	TPE – Thermoplastic Elastomer	23 mm	160 cm
No.4 metal mirror tube cavity	Laparoscopic irrigator	Medical stainless steel	3.0 mm	53 cm

2.2. Main instruments and materials

Temperature and Pressure Tester (≥ 6 channels, accuracy ± 0.1 ℃), Model: 4T/3TP, equipped with a miniature thermocouple probe.

2.3. Research methods

Sterility efficacy validation for lumen instruments: On each sterilizer across all hospital sites, a "maximum challenge load" (a mixed load simulating the daily maximum workload, including fabrics and metallic instruments) was applied. Micro thermocouple probes were positioned at the following locations:

(1) The most challenging areas for sterilization of lumen instruments (deepest lumen regions, joint interiors), secured using the puncture method or specialized mounting brackets;

(2) Above the drainage port in the sterilizer chamber (cold point);

(3) The central point;

(4) The center of the standard test kit. The standard lumen instrument program currently used by each sterilizer was executed to collect temperature-time curves and pressure curves.

2.4. Evaluation criteria

Physical parameters meet specifications: temperatures at all measurement points during the exposure phase fall within the range of + 0.5 ℃ to + 3.0 ℃ above the sterilization set temperature (e.g., 134 ℃), with a duration ≥ the specified exposure time (e.g., 4 min); the pressure curve conforms to the corresponding saturated vapor pressure-temperature relationship.

Moisture pack assessment: After sterilization and cooling, obvious visible water stains, droplets, or moist areas are observed on both the interior and exterior of the package, or the weight increases by > 1%.

3. Results

3.1. Validation of sterilization process effectiveness for lumen devices

As shown in **Table 2**, the three pre-vacuum pressure steam sterilizers from different brands exhibited distinct thermal transfer characteristics during the pulse phase, heating phase, and sterilization maintenance phase. For all types of lumenary instruments under Brand A, temperatures ranged from 55.9 ℃ to 63.1 ℃ during the initial pulse phase, significantly higher than the 26.1 ℃ recorded for the standard test package; during the heating phase, temperatures ranged from 53.3 ℃ to 57.9 ℃, nearly identical to those of the standard test package (56.3 ℃), with a heating duration of 246–251 seconds. Upon entering the sterilization maintenance phase, temperatures at all measurement points stabilized between 134.6 ℃ and 134.7 ℃, with a sterilization time of 317–326 seconds, fully meeting the specified temperature and exposure requirements. These results indicate that while lumenary instruments in Brand A devices experience rapid temperature rise during the early vacuum pulse phase, the standard test package achieves comparable temperature profiles during subsequent heating stages, resulting in excellent consistency of parameters across all measurement points during the final sterilization maintenance phase.

During the initial heating phase, Brand B exhibited more pronounced temperature increases in all luminal instruments: non-metallic lumen 1#, non-metallic lumen 2#, thick non-metallic lumen, and metallic endoscope lumen reached temperatures of 129.1 ℃, 130.8 ℃, 127.4 ℃, and 130.3 ℃, respectively, significantly higher than those of the standard test kit (24.9 ℃). During the heating phase, temperatures for all instruments ranged from 83.1 ℃ to 89.5 ℃ compared to 82.0 ℃ for the standard test kit, with heating durations concentrated between 693–696 seconds. In the sterilization maintenance phase, temperatures for all instruments and the standard test kit remained within the acceptable range of 135.2–135.4 ℃ over a sterilization time of 358–362 seconds. Although Brand B required significantly longer heating times than Brand A, its sterilization maintenance phase temperatures approached 135 ℃ with minimal inter-point variations, indicating superior temperature uniformity during this phase.

During the initial pulse phase of Brand C, the temperature of all lumen instruments ranged from 73.0 ℃ to 91.1 ℃, significantly higher than the 28.1 ℃ recorded for the standard test kit; during the heating phase, instrument temperatures reached 105.4–108.6 ℃ compared to 106.8 ℃ for the standard kit, with a heating duration of 477–493 seconds. During the sterilization maintenance phase, except for metal-lumen instrument #2, which registered 143.7 ℃, all other measurement points showed temperatures between 135.1 ℃ and 135.2 ℃; the sterilization time was 266–282 seconds, exceeding the conventional requirement of 240

seconds. Overall, all three brands of sterilizers achieved effective sterilization temperatures and durations for both lumen instruments and standard test kits during the maintenance phase, though variations were observed among devices regarding initial heating levels, heating duration, and temperature fluctuations during the pulse phase.

Table 2. Parameters for various types of medical devices during the sterilization process, including pulse cycles, temperature rise, and sterilization maintenance phases

Sterilizer	Device type	Temperature during the first pulse phase (℃)	Temperature during the heating phase (℃)	Heating-up time (s)	Sterilization temperature (℃)	Sterilization time (s)
Brand A	non-metallic lumen 1#	60.3	57.4	246	134.6	325
	non-metallic lumen 2#	57.9	56.5	247	134.6	326
	Coarse non-metallic lumen	55.9	53.3	250	134.6	322
	Metal endoscopic luminal tube	63.1	57.9	246	134.7	324
	Standard Test Package	26.1	56.3	251	134.6	317
Brand B	non-metallic lumen 1#	129.1	83.6	695	135.2	359
	non-metallic lumen 2#	130.8	84.4	693	135.3	362
	Coarse non-metallic lumen	127.4	89.5	696	135.3	358
	Metal endoscopic luminal tube	130.3	83.1	693	135.3	361
	Standard Test Package	24.9	82	693	135.4	362
Brand C	Non-metallic lumen 1#	91.1	105.4	477	135.2	275
	Non-metallic lumen 2#	87.1	108.4	477	143.7	282
	Coarse non-metallic lumen	73	108.6	493	135.1	266
	Metal endoscopic luminal tube	88	105.9	481	135.2	280
	Standard Test Package	28.1	106.8	481	135.2	281

3.2. Parameter validation during the sterilization and drying stage

As shown in **Table 3**, there are significant variations in average temperatures during the drying phase across different sterilizers and instrument types. Brand A exhibited an average drying time of 1662 seconds, with average temperatures ranging from 47.3 ℃ to 62.1 ℃ at all measurement points: the standard test package recorded the lowest temperature (47.3 ℃), while non-metallic cavity 1# showed the highest temperature (62.1

℃); non-metallic cavity 2#, coarse non-metallic cavity, and metallic endoscope cavity had temperatures of 55.4 ℃, 58.7 ℃, and 54.8 ℃, respectively. Brand B achieved the longest average drying time among the three devices at 1695 seconds, with temperatures ranging from 52.7 ℃ to 64.5 ℃; the coarse non-metallic cavity recorded the highest temperature (64.5 ℃), while the standard test package had the lowest (52.7 ℃). Brand C demonstrated a significantly shorter average drying time of 1286 seconds, with average drying-stage temperatures ranging from 56.1 ℃ to 92.9 ℃; non-metallic cavity 1# recorded the highest temperature (92.9 ℃), whereas the metallic endoscope cavity had the lowest temperature (56.1 ℃).

A comprehensive comparison reveals that although both Brand A and Brand B have drying times exceeding 1600 seconds, the average temperature during the drying phase for most luminal devices and standard test kits remains concentrated between 47.3 ℃ and 64.5 ℃, indicating that extended drying time does not necessarily lead to simultaneous temperature increases across all loading sites. Brand C has the shortest drying time, yet temperatures in some non-metallic luminal devices rise significantly, highlighting differences in hot air circulation, moisture removal efficiency, and heat dissipation characteristics among different equipment drying protocols. The standard test kit consistently operates at lower temperature points in both Brands A and B, whereas flexible non-metallic luminal devices exhibit considerable temperature fluctuations across brands, demonstrating that drying risks are influenced not only by device material but also by luminal structure, loading position, equipment drying logic, and moisture removal capacity.

Table 3. Parameters of various instruments during sterilization and drying processes

Sterilizer	Device Type	Average temperature during the drying process (℃)	Average drying time (s)
Brand A	Non-metallic lumen 1#	62.1	1662
	Non-metallic lumen 2#	55.4	
	Coarse non-metallic lumen	58.7	
	Metal endoscopic luminal tube	54.8	
	Standard Test Package	47.3	
Brand B	Non-metallic lumen 1#	59.3	1695
	Non-metallic lumen 2#	55.8	
	Coarse non-metallic lumen	64.5	
	Metal endoscopic luminal tube	57.4	
	Standard Test Package	52.7	
Brand C	Non-metallic lumen 1#	92.9	1286
	Non-metallic lumen 2#	62.3	
	Coarse non-metallic lumen	64.6	
	Metal endoscopic luminal tube	56.1	
	Standard Test Package	60.8	

4. Discussions

4.1. Differences and significance of sterilization process parameters between standard dressing kits and lumenary instruments

This study found that all three sterilizers exhibited slower temperature rise in the standard test pack compared to lumen instruments during the initial pulse phase. The standard test pack, composed of multiple layers of fabric with high mass and thermal storage capacity, along with extended air evacuation and steam penetration

pathways, resulted in delayed early heating; whereas lumen instruments, despite their complex structure, have lower overall thermal capacity and heated more rapidly upon steam exposure. These findings indicate that low temperatures during the early pulse phase cannot directly classify lumen instruments as higher-risk loads.

Upon entering the heating and sterilization maintenance phase, both the standard test pack and various luminal devices gradually converge in their parameters, with all exposure times meeting the specified requirements. This demonstrates that under the loading conditions and sterilization protocol employed in this study, the standard dressing pack presents greater challenges during the heating phase compared to luminal devices; when the standard dressing test pack achieves qualified parameters during heating and sterilization maintenance, all luminal devices generally meet compliance criteria simultaneously. Therefore, the primary risk associated with special luminal devices in this study lies not in insufficient sterilization temperature or exposure time. The sterilization qualification of dressings or disposable PCD dressings can serve as a reliable indicator of sterilization compliance. Consequently, quality control efforts should shift from solely focusing on sterilization compliance to encompassing residual moisture during the drying phase, steam emission, and risk management for wet dressings.

4.2. Possible mechanisms of wet packaging risk in Brand C non-metallic Lumen pipes

The drying phase better reflects the actual quality risks associated with specialized luminal instruments. Brand C exhibited an average drying time of 1,286 seconds, shorter than Brands A and B; however, some non-metallic lumens showed higher average temperatures, with Non-metallic Lumen 1 reaching 92.9 ℃. This suggests that moisture retention is not solely due to insufficient temperature but may be related to drying duration, moisture removal capacity, and condensation accumulation within the lumen. The thermal conductivity, heat dissipation, and resilience characteristics of non-metallic flexible lumens differ from those of metallic instruments. If the lumen is folded, low-level fluid accumulation occurs, or exhaust at both ends is obstructed, residual vapor can maintain elevated local temperatures for extended periods without complete moisture removal.

Therefore, the average temperature during the drying phase should not be used alone as a criterion for assessing drying adequacy; it must be evaluated comprehensively in conjunction with drying time, loading position, packaging tightness, cavity opening orientation, and visual inspection results after cooling. For processes with short drying times or high wet packet formation rates, drying duration and loading limits should be optimized based on validation to prevent cavity folding and low-level water accumulation while maintaining open ends. Additionally, dedicated wet packet records and trend analyses should be established for non-metallic long cavities.

In summary, the focus of risk control for specialized luminal devices should expand from “whether sterilization parameters are achieved” to “whether adequate drying occurs post-sterilization”. Standard test kits serve as critical challenge specimens during the sterilization phase, whereas non-metallic lumens should be prioritized as key risk areas during the drying stage. Integrating parameter validation, loading intervention, wet package tracking, and continuous improvement into a unified closed-loop system enhances process control stability across different devices and loading conditions.

4.3. Limitations

This study represents a field validation conducted within a single healthcare group, with limited samples of devices and instruments, and did not include long-term follow-up or comparison of wet pad incidence rates before and after intervention. Future studies should expand the sample size, conduct multicenter, repeated-measurement trials, and evaluate the efficacy of drying protocols and loading optimization measures in terms

of wet pad outcomes.

5. Conclusion

Under the loading and sterilization conditions employed in this study, both specialized lumen devices and standard dressing test kits achieved the specified temperature and exposure time during the sterilization maintenance phase without demonstrating an increased risk of sterilization failure. The standard test kit exhibited slower temperature rise during the initial pulse phase, serving as a significant challenge for the sterilization process. Under these loading conditions and sterilization protocols, specialized lumen devices did not demonstrate a higher sterilization failure risk compared to standard dressings; when standard dressing test kits met the required sterilization parameters, the sterilization temperature and duration for lumen devices typically also complied with specifications. Therefore, quality control of lumen devices should focus not only on compliance during sterilization but also on post-sterilization drying adequacy and wet pack risks.

The primary differences among various devices lie in the drying phase. Even with shorter drying times and higher local temperatures, inadequate moisture removal may still occur, particularly in flexible non-metallic long luminal tubes. It is recommended to employ standard test kits for monitoring during sterilization, prioritize non-metallic luminal structures as key drying risk areas, and establish a comprehensive quality control system based on risk assessment by optimizing procedures and loading protocols, maintaining luminal patency, enhancing post-cooling inspections, and implementing wet package tracking.

Disclosure statement

The authors declare no conflict of interest.

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