

Evaluation of the bacteriological effectiveness of sterilization of reusable medical devices at the Sourô SANOU University Hospital Center, Bobo-Dioulasso, Burkina Faso.

Évaluation de l'efficacité bactériologique de la stérilisation des dispositifs médicaux réutilisables au Centre Hospitalier Universitaire Sourô SANOU, Bobo-Dioulasso, Burkina Faso.

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Abstract

Objective: Healthcare-associated infections are among the leading causes of morbidity and mortality worldwide. The sterilization of medical devices in hospitals is therefore essential in the fight against these infections. This study aimed to evaluate the bacteriological effectiveness of sterilization at the Sourô SANOU University Hospital Center in Bobo-Dioulasso, Burkina Faso. **Methods:** This was a cross-sectional analytical study conducted in the central sterilization unit and the bacteriology laboratory. Data were collected through observation of practices and laboratory analyses. The evaluation of practices was based on the French guide to good hospital pharmacy practices. **Results:** Several shortcomings were identified: failure to comply with hygiene and protection measures, obsolete equipment, use of dry heat, and lack of certain controls. The overall non-compliance rate was 44.6%. Bacteriological analyses revealed the presence of 12 *Staphylococcus* isolates, including 3 *Staphylococcus aureus* and 9 *Staphylococcus epidermidis*. Storage duration was the only factor independently associated with post-sterilization contamination. (Adjusted OR=5.9; 95% CI: 1.2-28.4; p=0.025). **Conclusion:** This study highlights shortcomings in sterilization practices at Sourô SANOU University Hospital, which could compromise the quality of care and the safety of patients and healthcare professionals, leading to an increase in healthcare-associated infections.

Key words: bacteriological effectiveness, sterilization, reusable medical devices, University Hospital Burkina Faso.

Résumé

Objectif : Les infections associées aux soins figurent parmi les principales causes de morbidité et de mortalité dans le monde. La stérilisation des dispositifs médicaux dans les hôpitaux est donc primordiale pour la lutte contre ces infections. Cette étude visait à évaluer l'efficacité bactériologique de la stérilisation au Centre Hospitalier Universitaire Sourô SANOU, à Bobo-Dioulasso au Burkina Faso. **Méthodes :** Il s'est agi d'une étude transversale analytique qui s'est déroulée dans l'unité centrale de stérilisation et le laboratoire de bactériologie. Les données ont été recueillies par observation des pratiques et analyses de laboratoire. L'évaluation des pratiques s'est appuyée sur le guide français des bonnes pratiques de pharmacie hospitalière. **Résultats :** Plusieurs insuffisances ont été identifiées : non-respect des mesures d'hygiène et de protection, équipements obsolètes, usage de chaleur sèche et absence de certains contrôles. Le taux global de non-conformité était de 44,6 %. Les analyses bactériologiques ont révélé la présence de 12 isolats de *Staphylococcus*, dont 3 *Staphylococcus aureus* et 9 *Staphylococcus epidermidis*. La durée de stockage était le seul facteur associé à la contamination post-stérilisation (OR ajusté = 5,9 ; IC à 95 % : 1,2-28,4 ; p = 0,025). **Conclusion :** Cette étude met en évidence des lacunes dans les pratiques de stérilisation au Centre Hospitalier Universitaire Sourô SANOU, qui pourraient compromettre la qualité des soins, la sécurité des patients et des professionnels de santé.

Mots clés : efficacité bactériologique, stérilisation, dispositifs médicaux réutilisables, Hôpital Universitaire Burkina Faso.

INTRODUCTION

Healthcare-associated infections are a major cause of morbidity and mortality worldwide, with a disproportionate burden in developing countries, where they generate significant economic and social costs [1]. These infections occur during or after patient care and were neither present nor incubating at the start of care [2]. Non-compliance with sterilization requirements for reusable medical devices is a major contributing factor [3]. Sterilization aims to eliminate all microorganisms from a thoroughly cleaned object; inadequate procedures may allow the persistence of fungi, bacteria, viruses or spores capable of causing infection [4]. From an epidemiological perspective, healthcare-associated infections remain a serious public health concern globally. In the United States, approximately 700,000 cases are reported annually. A multicountry study conducted in 173 intensive care units across Latin America, Asia, Africa and Europe estimated the economic burden of infections associated with medical devices at US\$ 1.5 billion [5, 6]. The growing spread of antimicrobial resistance, which limits therapeutic options, further underscores the importance of prevention as the most effective strategy to reduce both the direct and indirect costs of these infections [5]. Proper sterilization of reusable medical devices, would effectively contribute to the prevention of healthcare-associated infections. Indeed, Rutala and Weber in 1999 [3] as well as Geehan Suleyman et al. in 2018 [7] have shown that in facilities where staff are regularly trained in good sterilization practices, the incidence of healthcare-associated infections is significantly lower. Studies conducted in seven tertiary referral hospitals in Mali and Senegal have highlighted shortcomings in staff practices and behaviors with regard to the required sterilization standards [8]. These shortcomings have a direct impact on user safety. Similarly, the work of Ango et al. in the intensive care unit of the University Hospital Center in Treichville [9], those of Ouendo et al. at the National University Hospital Center in Cotonou, Benin [10], as well as those of Dossim et al. at the Sylvanus Olympio University Hospital Center in Lomé, Togo, have highlighted significant shortcomings in the sterilization process, notably resulting in the detection of microorganisms on devices that are supposed to be sterile. In Burkina Faso, the only studies

reporting on the evaluation of the sterilization of reusable medical devices in the literature were conducted in two university hospitals in Ouagadougou, namely the Yalgado Ouédraogo University Hospital [11] and the Charles de Gaulle Pediatric University Hospital Center [12] which revealed numerous shortcomings in terms of equipment and organization. This lack of data in Bobo-Dioulasso, combined with non-compliant practices reported both locally and, in the subregion, raises questions about the effectiveness of sterilization for reusable medical devices in our practice setting in Bobo-Dioulasso. This study therefore aims to evaluate the quality of the sterilization process for reusable medical devices. Specifically, its objectives are to describe the sterilization methods used, determine the prevalence of bacterial contaminants present on instruments after treatment, and identify the factors associated with the contamination of reusable medical devices after treatment.

METHODS

❖ Study design and framework

This cross-sectional analytical study was conducted at the Sourô SANOU University Hospital Center in Bobo-Dioulasso, Burkina Faso, from September 1, 2024, to February 28, 2025. Practices were evaluated and samples collected in the surgery department's sterilization unit. Bacteriological analyses were performed in the Bacteriology-Virology unit, which houses the National Reference Laboratory for Antimicrobial Resistance.

❖ Target material and source material

The study included all reusable medical devices processed in the sterilization department of the Sourô SANOU University Hospital Center. The main items sterilized were surgical instruments and drapes. Instruments included those for appendectomy, laparotomy, bone surgery, microsurgery, amputation, urology, and small tools such as forceps, scissors, suction probes, and compresses.

❖ Sample size and sampling

The method involved swab sampling on individually packaged instruments and on several instruments grouped together in containers (boxes). Some of the samples were taken immediately after sterilization, while others were taken after a period of storage. Samples taken immediately after sterilization were included in the category of devices that had been stored for less than five days, without

any specific distinction as to the exact duration of storage. The instruments to be sampled were selected using convenience sampling. The formula used to obtain the minimum sample size was as follows:

$$n = \frac{\mu^2 N \pi (1-\pi)}{(N-1)\epsilon^2 + \mu^2 \pi (1-\pi)};$$

In this expression:

- n = sample size
- $\mu = 1.96$ for a confidence level set at 95%
- $N = 300$ is the number of containers sterilized per month, at a minimum rate of 1 cycle of 10 containers per day for both the autoclave and the Poupinel.
- $\Pi = 0.35$ corresponding to the non-compliance rate
- ϵ = the estimated margin of error of 5%. We obtained a sample size of 162 samples. Out of the 162 samples, some were collected from the storage room on sterile instruments that had been stored for more than 5 days ($n=80$) and others on instruments that had been stored for less than 5 days ($n=82$).

❖ Data collection

Study variables

Dependent variables: the result of the bacteriological culture of the sample

- Positive, if bacteria are present
- Negative, if bacteria are absent

Explanatory variables:

- Sterilization method: classified into two categories, namely moist heat sterilization and dry heat sterilization.
- Source of instruments: the instruments came from different departments, including orthopedics, ophthalmology, visceral/digestive surgery, pediatric surgery, dermatology, urology, and the department of gynecology, obstetrics, and reproductive medicine.
- Storage duration: this was conveniently categorized into two classes: ≤ 5 days and > 5 days.
- Packaging method: classified into two types, namely containers and sterilization pouches.

Method of collection

Data was collected through direct observation of practices within the central sterilization department and using laboratory analysis results.

Electronic data collection and recording tool

This data was collected using an observation grid based on the French hospital pharmacy good practices guide [13] as well as in a lab

notebook for the results of laboratory analyses. The observation grid included (supplementary file 1):

- Eight criteria for pre-disinfection compliance
- Ten criteria for cleaning compliance (washing, rinsing, drying)
- Eleven criteria for compliance with packaging and labelling
- Eleven criteria for compliance with sterilization aspect
- Seven criteria for compliance with storage and transport
- Seven criteria for compliance with process validation and control.

Sampling and bacteriological analysis of samples

Samples were collected from instruments presumed sterile using single-use sterile swabs, applied with linear or zigzag motions, sometimes in two directions while rotating the swab. Instruments were placed in labeled containers, with 1 swab used for small containers and 2–3 swabs for large ones. Swabs were moistened with 0.9% NaCl and labeled with origin, date, time, storage duration, packaging type, and sterilization method. Each swab was soaked in 1 ml of sterile saline to prepare a bacterial suspension, returned to sterile tubes, and sent to the laboratory for same-day inoculation to prevent deterioration. Samples were cultured on chocolate agar and incubated 18–24 hours at 37°C in a CO₂ incubator. Isolates were identified based on morphological, cultural, and biochemical characteristics. Antibiotic susceptibility testing was performed only for isolated strains of *S. aureus*, which are major opportunistic pathogens often responsible for serious nosocomial infections. Although *S. epidermidis* is commonly found on instruments, it is generally not very pathogenic and its isolation does not indicate a significant risk of infection. This choice allows the assessment to focus on the most relevant clinical risk. Antibigrams were performed using the Kirby-Bauer agar diffusion method, according to French Society of Microbiology recommendations (2024) [14].

❖ Statistical analyses

Data were entered into Microsoft Excel 2021 and analyzed using SPSS version 25. Each stage of the sterilization process was assessed against the reference standard, with non-compliance rates calculated as the number of

non-compliant criteria divided by the total criteria per stage. The prevalence of contaminated instruments was determined by comparing positive bacteriological cultures to the total samples collected post-sterilization. Logistic regression (univariate and multivariate) identified factors associated with contamination. In univariate analysis, instrument characteristics (sterilization method, origin, storage time, packaging) associated with non-sterility at a 20% threshold were included in multivariate analysis. The significance level was set at $p < 0.05$ for all tests.

❖ Ethical and regulatory considerations

The study poses no danger to the population under study. On the contrary, the results will enable appropriate measures to be taken to improve activities in the sterilization department. Authorization to carry out this work has been obtained from the senior management of the Sourô SANOU University Hospital Center (supplementary file 2).

RESULTS

❖ Description of sterilization methods for reusable medical devices

Pre-disinfection was performed manually within 5–15 minutes after use in uncovered trays containing a detergent–disinfectant solution (ANIOS) at recommended concentrations, with soaking for at least 15 minutes. The dedicated area was shared with other treatment activities. Procedures for pre-disinfection and cleaning were displayed, unlike those for other processing steps, and the use of appropriate personal protective equipment was not enforced. Cleaning, carried out in the same solution, involved manual brushing, rinsing, temporary storage and open-air drying, followed by wiping with a reused towel. Instrument integrity was checked at the end of the process. Non-compliance rates were 33.3% for pre-disinfection and 36.4% for cleaning. After drying and inspection, instruments were packaged in sterilization pouches for moist heat sterilization or in containers for moist or dry heat sterilization. Some containers lacked tamper-evident devices, and secondary packaging for pouched instruments was not systematically applied. Packaging was performed in the same area as washing, without appropriate personal protective equipment. Boxes were consistently labeled before sterilization. Non-compliance rates were 40% for packaging and 0% for labeling. The central sterilization unit of the

Sourô SANOU University Hospital Center used dry heat (poupinel) and moist heat (autoclave) sterilization methods. Both devices were faulty and poorly maintained. The autoclave operated with only two heating elements instead of three following a technical modification and presented persistent drying failures, resulting in residual water in some supposedly sterile boxes. Despite this, operating instructions were followed, with cycles set at 134°C for at least 18 minutes or 125°C for at least 20 minutes for heat-sensitive devices. The poupinel doors did not close properly, requiring external support. Manufacturer instructions were not respected, as sterilization lasted two hours at 180°C instead of 60 minutes due to lack of airtightness. Overall, the sterilization step showed a non-compliance rate of 55.5%. Sterile devices were stored on simple shelves in a separate but contamination-exposed area. The storage environment was dusty, including inside some boxes kept for prolonged periods, resulting in a non-compliance rate of 66.7%. Transport to clinical departments was performed using poorly maintained trolleys and wheelchairs, with a non-compliance rate of 100%. Indicator switching verification, post-start cycle monitoring, and load validation were correctly performed. However, steam penetration (Bowie–Dick), leak testing and post-cycle chart analysis were not conducted, resulting in a non-compliance rate of 42.9%. The non-compliance rates for the various stages of processing reusable medical devices are shown in the figure below (Figure 1). The overall non-compliance rate was 44.6% (Figure 1).

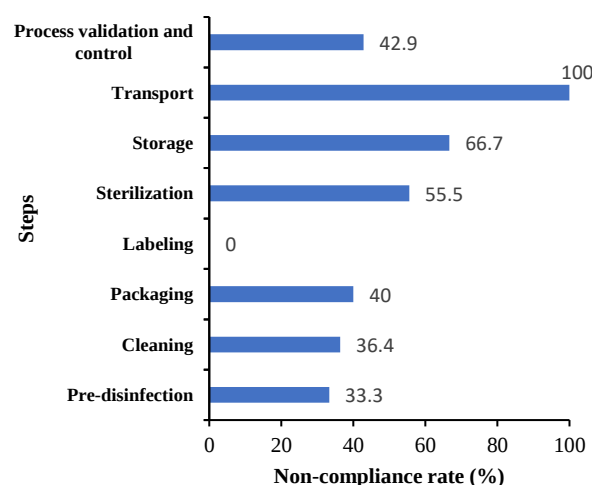


Figure 1: Non-compliance rates for the various stages of processing reusable medical devices.

❖ Characteristics of the samples collected

A total of 162 swab samples were taken from reusable medical devices presumed to be sterile from the seven (07) departments mentioned in the methodology section. Out of the 162 samples, 83 (51.3%) were sterilized using the dry heat method, with the vast majority (44.4%) coming from the orthopedics department. There were 142 reusable medical devices packaged in containers, representing a frequency of 87.7% (142/162). Considering the storage time of the reusable medical devices, 82 samples were taken from those that had been in the storage area for less than 5 days, representing 50.6% (82/162). (Table 1).

Table 1: Distribution of samples according to the characteristics of the instruments collected

Variable	Staffing levels	Frequency (%)
Sterilization methods		
Moist heat (autoclave)	79	48.7
Dry heat (poupinel)	83	51.3
Origin of the instruments		
Orthopedics	72	44.4
Ophthalmology	6	3.7
Visceral/digestive surgery	34	20.9
Pediatric surgery	13	8.0
Dermatology	1	0.6
Urology	29	17.9
Gynecology, obstetrics, and reproductive medicine	7	4.3
Storage life		
Time > 5 days	80	49.4
Time ≤ 5 days	82	50.6
Packaging method		
In container	142	87.7
Under sterilization sleeve	20	12.3

❖ Bacteriological Results

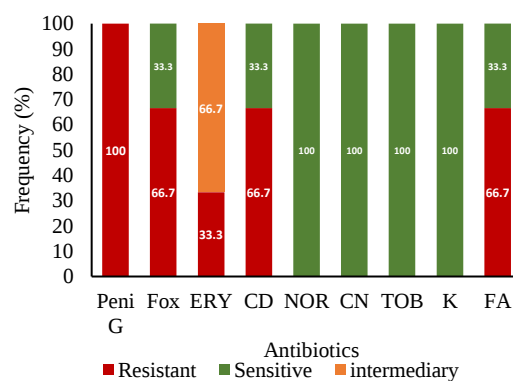
Prevalence of bacterial contaminants isolated from reusable medical devices presumed to be sterile after processing

Out of the total 162 samples analyzed, 12 samples were tested positives in culture, representing a bacteriological yield of 7.4%

(12/162). The bacterial species identified included 75% of isolates (9/12) of *Staphylococcus epidermidis* and 25% of isolates (3/12) of *Staphylococcus aureus*. We performed antibiotic susceptibility testing only on potentially pathogenic *S. aureus* strains. The *S. aureus* isolates were resistant to Penicillin G, Cefoxitin, Clindamycin, and Fusidic acid with respective frequencies of 100% and 66.7%. However, the isolates remained susceptible to gentamicin, tobramycin, and kanamycin at a frequency of 100% (Figure 2).

Factors associated with contamination of reusable medical devices after processing

No contamination was observed among reusable medical devices from dermatology and ophthalmology departments. Similarly, no instruments in sterilization sleeves were contaminated. Multivariate analysis showed that only storage time was associated with contamination of reusable medical devices after treatment (adjusted OR=5.9; 95% CI: 1.2-28.4; p=0.025). Other factors such as sterilization method, department of origin, and packaging method were not statistically significant (Table 2).



Peni G: Penicillin G; Fox: Cefoxitin; ERY: Erythromycin; CD: Clindamycin; NOR: Norfloxacin; CN: Gentamicin; TOB: Tobramycin; K: Kanamycin; FA: Fusidic acid

Figure 2: Antimicrobial resistance of isolates

Table 2: Factors associated with contamination of reusable medical devices after processing

Variable	Staffing levels Positive (Frequencies)	Crude odds ratio (95%IC)	Univariate p-value	Adjusted OR (95% CI)	Multivariate p-value
Sterilization methods					
Moist heat (autoclave)	3 (3.79)	1	0.124	1	0.107
Dry heat (poupinel)	9 (10.84)	2.9 (0.7-11.1)		3.1 (0.8-12.1)	
Origin of the instruments					
Orthopedics	6 (50)	1	0.215	-	-
Visceral/digestive surgery	1 (8.33)	2.0 (0.3-11.2)		-	-
Pediatric surgery	2 (16.66)	0.3 (0.1-2.9)		-	-
Urology	1 (8.33)	4.4 (0.7-27.7)		-	-
Department of gynecology, obstetrics, and reproductive medicine	2 (16.66)	0.4 (0.1-3.4)		-	-
Storage life					
Time > 5 days	10 (12.5)	1	0.029	1	0.025
Time < 5 days	2 (2.4)	5.7 (1.2-26.8)		5.9 (1.2-28.4)	

DISCUSSION

This study aimed to evaluate the sterilization process for reusable medical devices at the Sourô SANOU University Hospital Center, identifying non-compliant practices and factors likely to compromise instrument sterility, with the objective of improving patient and staff safety. The evaluation revealed multiple shortcomings at different stages of the sterilization process. Pre-disinfection presented a risk of confusion between dirty and clean devices due to the absence of separated areas and non-compliance with forward flow, as previously reported by Sombié et al. in 2022 [11] at the Charles de Gaulle Pediatric University Hospital Center in Ouagadougou, Burkina Faso, and by Bahri et al. during an audit in two Tunisian hospitals [15]. In addition, appropriate personal protective equipment for pre-disinfection was not used. These findings highlight the need to equip sterilization units and operating rooms with adequate materials and to ensure staff training. Cleaning also showed several shortcomings that could compromise the effectiveness of the overall process. It was performed manually by brushing, although NF EN ISO 15 883-2 standards no longer recommend manual cleaning due to its limited standardization and reproducibility, as well as the increased risk of contamination and injury to staff. Nevertheless, it may remain useful for fragile or complex devices. Similar practices were reported by Traoré et al. [8] and Sombié et al. [11]. However, the absence of recommended protective equipment exposes staff to avoidable risks. The acquisition of a washer-disinfector could improve both cleaning quality and occupational safety.

Drying and packaging, which are critical steps following cleaning, also showed deficiencies. Drying was performed in open air with wiping using reused towels, a practice previously reported by Déhainsala et al. in 2010 at the Yalgado Ouédraogo University Hospital Center in Ouagadougou, Burkina Faso [12]. Packaging practices were marked by the absence of secondary packaging for instruments packaged in sheaths and the lack of tamper-evident devices, as also noted by Traoré et al. [8] and Sombié et al. [11]. Sterilization, the decisive step in ensuring device sterility, was also affected by practices that could compromise its effectiveness. Dry heat sterilization using a poupinel was still widely used. Although

potentially effective under optimal conditions, this method is prohibited in healthcare facilities in some countries, particularly in France, due to its limitations, including ineffectiveness against unconventional transmissible agents and fixation of prion infectivity. It should therefore be replaced by steam sterilization to ensure patient and staff safety. Déhainsala et al. [12] similarly reported the use of dry heat sterilization in Ouagadougou. In addition, the absence of periodic requalification and preventive maintenance of equipment, also reported at the Charles de Gaulle Pediatric University Hospital Center [11], could compromise device sterility and increase occupational risks. Even when sterilization is adequately performed, storage and transport remain critical points. The storage area was poorly maintained, with dust present, increasing the risk of recontamination, as also observed at the Charles de Gaulle Pediatric University Hospital Center [11]. This situation may be related to inadequate infrastructure design and insufficient staff training. Transport was carried out using poorly maintained wheelchairs, often due to limited resources or lack of awareness of associated risks, potentially compromising sterility, particularly for containers without tamper-evident devices. Furthermore, several essential control procedures were missing, including periodic leak testing, post-cycle diagram analysis, and steam penetration testing (Bowie and Dick test), as previously observed at the Charles de Gaulle Pediatric University Hospital Center [11]. The absence of these controls and insufficient training may result in ineffective sterilization and the use of non-sterile medical devices, exposing patients and staff to infectious risks. The overall non-compliance rate compared with reference standards was 44.6%. Mohamed Hedi Ben Cheikh et al. [16] reported a higher rate of 71.9% at Tahar Sfar Hospital in Mahdia, Tunisia. The high non-compliance rate observed in our study may be explained by insufficient initial and continuing training, staff negligence, or limited resources for equipment acquisition and facility adaptation.

Bacteriological analysis performed after device processing showed a positivity rate of 7.4% among 162 samples, all Gram-positive (*S. aureus* and *S. epidermidis*). This rate is lower than that reported by Dossim S et al. at the Sylvanus Olympio University Hospital Center

in Lomé, Togo [17] who found a 40% positivity rate with a predominance of staphylococci. This could be explained by the fact that staphylococci are present in many places, including the environment and human epithelium. The dusty storage room promotes colonization by this type of bacteria. In addition, access by people outside the department could also be a factor in contamination, particularly when healthcare professionals enter the room and handle the containers freely without first complying with hygiene protocols. Furthermore, some containers are damaged or lack tamper-proof devices, which facilitates the intrusion of microorganisms.

Antibiogram results showed that *S. aureus* strains were resistant to Penicillin G, Cefoxitin, Clindamycin, and Fusidic acid, while remaining susceptible to aminoglycosides (gentamicin, tobramycin, kanamycin). Penicillin resistance mediated by penicillinase production has been well documented since the 1950s, with more than 90% of clinical strains currently resistant in many countries [18, 19]. In contrast, the preserved susceptibility to aminoglycosides is encouraging and may reflect more restricted use locally. Bacteriological findings emphasized the role of post-sterilization practices in device contamination. Statistical analysis identified storage time as the only factor associated with contamination, confirming that inadequate storage conditions can compromise sterility [20, 21]. Overall, this study provides valuable data on the sterilization process at Sourô SANOU University Hospital. While bacteriological effectiveness was generally satisfactory, the high rate of non-compliance, particularly in storage practices, is a major weakness. To reduce contamination of reusable medical devices, it is essential to strengthen sterilization in accordance with standards, regularly check equipment, and ensure strict compliance with hygiene procedures by staff. A methodological limitation of this study is that samples could not be collected in a clean room, which was a technical constraint. However, strict precautions were taken to minimize external contamination, including the use of sterile equipment, adherence to aseptic procedures, and limiting exposure time. Furthermore, the absence of environmental sampling (air, surfaces, staff hands) is an additional limitation, as it would have made it

possible to identify possible additional sources of contamination.

CONCLUSION

Sterilization of medical devices is crucial to prevent healthcare-associated infections, as surfaces and devices are frequently colonized by microorganisms from the environment, patients, or staff. Post-sterilization evaluation identified several non-compliances and characterized the bacterial reservoir at the Sourô SANOU University Hospital Center. *S. aureus* and *S. epidermidis* were isolated, and storage time was the only factor associated with contamination. These findings emphasize the need for continuous monitoring, improved sterilization practices, and national regulations to strengthen systems and ensure quality care in Burkina Faso.

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