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# *"Evaluation of current sterilization and disinfection methods for medical devices in terms of effectiveness, safety, and material compatibility"*

***Kothwala Dr. Deveshkumar Mahendralal, Pathak Vipul & Saurabh Barik***
*Meril Medical Innovations Private Limited, Bilakhia House, Survey No.879, Muktanand Marg, Chala, Vapi, Dist- Valsad, Gujarat, 396191, India.*

**Abstract**

The procedure of completely eliminating or eradiating all the micro organisms, such as virus, fungi, and bacteria from the surface or the object are known as sterilization. Disinfection is the process of thoroughly eliminating or reducing pathogenic microorganisms on the inanimate objects or the surface areas to a certain level, where it is not hazardous or harmful to human health, typically using chemical agents or any physical methods. The procedure does not necessary destroy the all microbial organisms, especially resistant bacterial spores. Effective Sterilization and Disinfection are essential for the safety and reusability of medical devices and preventing Healthcare Associated Infections ($HAI_S$).Sterilization destroys all kinds of the microorganisms. In contras disinfection lowers the microbial obligation to safer levels. Ethylene oxide (ETO), steam (autoclave), radiation, and low-temperature hydrogen peroxide plasma are the common sterilization techniques. Each of these method, they varies in suitability based on the device materials, efficacy, and clinical applications. The survey highlights the need for the continued evaluation of decontamination strategies to balance the microbial efficacy, material safety, and environmental considerations. Recent developments like supercritical $CO_2$ sterilization, UV radiation, and ozone aim at improving sustainability and efficiency. Despite the developments, concerns like Multidrug resistance organisms ($MDRO_S$), hazardous residues, and sustainability concerns with single-use device remain. The advancement of safer, more economical and ecological sound sterilizing procedures which ensure patient safety and preserve the concept of infection control in changing medical facilities requires constant study.

**Keywords:** Healthcare Associated Infections ($HAI_S$), Ethylene Oxide (ETO), Multidrug Resistance Organisms ($MDRO_S$), Ultra Violet (UV) Radiation, Disease Control and Prevention (CDC), Tryptic Soy Agar (TSA).

**Introduction**

In past, methods such as autoclaving and chemical disinfection formed the foundation of the sterilization practices [1]. As every other approach, these traditional techniques have their limitations, particularly with regard to heat-sensitive instruments, toxic residues, process time, and compatibility with the modern device materials. However, as medical devices have transforms the backbone of sterilization process [2]. Furthermore, as medical devices have been evolved with the overview of minimally invasive tools, endoscope, and advanced implants, the requirement for the more adaptable and precise sterilization technologies has intensified.

As a result to these challenges, a moment of rushing trends and innovations is transforming the framework of sterilization and disinfection [3]. The ozone based sterilization, low temperature hydrogen peroxide plasma systems, nanotechnology, and UV-C radiation, driven antimicrobial coating are acquiring importance for their seed, efficiency, and environmental compatibility. At the same time, smart technologies, such as automated reprocessing systems, digital tracking, and real time monitoring are enhancing control, compliance, and efficiency in sterilization workflows [4]. Regardless the effectiveness of existing sterilization and disinfection method, challenges remain. The increasing prevalence of multidrug organisms ($MDRO_S$) and possible danger correlated with contaminated medical devices emphasizing the need for ongoing development in decontamination strategies. Regulatory organizations such as centers for disease control and prevention (CDC) allocates guidelines to ensure compliance with sterilization protocols, even though healthcare facilities often came across with the practical difficulties in maintaining stringent infection control measures.

Currently in modern healthcare system Sterilization and Disinfection medical equipments are essential, they are serving pivotal role in preventing $HAI_S$, ensuring patient safety, and maintaining the clinical efficacy [5]. The importance of these processes has increased considerably with the growing complexity of medical procedures, the application of sophisticated instruments, and the global emphasis on infection control, particularly in the wake of recent pandemics. The future prospective focuses on enhancing more sustainable and cost-effective sterilization techniques, while responding to the limitation of the existing methods. The incorporation of artificial intelligence (AI) and real time monitoring systems in the sterilization processes can improvise safety, traceability, and productivity [6]. Furthermore, the rising use of single-use medical devices promotes the concern about environmental sustainability, triggering the need for biodegradable devices raises concern about environmental renewability, encouraging the need for biodegradable materials and advanced the sterilization strategies that support device renewability without compromising patient safety.

As the technology advances, the application of the innovative sterilization techniques, enhanced regulatory compliance, and improved monitoring system which will plays the Pivotal role in enhancing infection control measures [7]. Prolonged research and collaboration amid the healthcare institution, regulatory bodies, and the manufactures are essential for addressing the current challenges and creating the future of sterilization and disinfection in healthcare practice.

**Selection of Medical devices for sterilization and disinfection**

A different range of renewable medical devices was selected for this study, classified according to the Spaulding classification system. Critical semi-critical and non-critical devices were evaluated to determine the most relevant sterilization or disinfection technique [8]. Example of the medical devices includes:

- **Critical devices:** Surgical instruments, catheters, and implantable devices are considered as critical devices.
- **Semi-critical device**: Endoscope, respiratory therapy equipment, and laryngoscope blades are the semi critical device.
- **Non-critical devices:** Blood pressure, hospital beds, and stethoscopes cuffs are the non critical devices.

The selection criteria reviewed the materials, complexity, and microbial contamination risks associated with each device type.

**Method and Material:**

This study was executed to examine the effectiveness, utilization, and comparative advantages of various sterilization and disinfection process used for medical equipments. The research emphasize on various sterilization methods utilized for medical equipments, such as autoclave, ETO, radiation sterilization, and hydrogen peroxide plasma sterilization. Moreover, various disinfection procedures were evaluated based on their microbial efficacy, material capability, and practical implementation [9].

- **Sterilization Methods:**

1. **Steam sterilization (Autoclave):**

- For many renewable medical devices stem sterilization remains the gold standard due to its high efficacy and speed [10].The procedure was proceed at 121° C for 15 minutes or 134° C for 3-5 minutes under high pressure, which effectively destroys all of the microorganisms, including bacterial spores. The whole process gets performed within three phases.
- Pre-vacuum phase: During the process removal of air from the chamber to be sure the steam penetration happens.
- Exposure phase: In this phase, at a high pressure saturated steam process of maintenance gets carried out.
- Drying phase: During this phase the residual moisture gets evaporated to prevent the post sterilization contamination.

**Advantages:**

- Rapid and reliable
- No toxic residue

**Limitations:**

- Not appropriate for the heat-sensitive devices
- Can cause warping or degradation of plastics and electronic components.

**Validation:**

- A biological indicators use *Geobacillus stearothermophilus* validates sterility [11].

**2. Ethylene Oxide (ETO) Gas Sterilization:**

Devices which are heat and moisture sensitive are sterilized by ETO sterilization [12]. The process gets performed at 30–60° with 30-50% relative humidity for 4-6 hours, ETO effectively break through lumens and complex structures. Devices were placed in sealed chamber, where ETO gas was introduced. The sterilization process continues with the diffusion phase, where gas penetrate the medical devices to disrupt the microbial DNA, and during the aeration phase, post sterilization process gets thoroughly gets proceed.

**Advantages:**

- Corporative with all most of the materials.
- Efficient for complex device geometries [13].

**Limitation:**

- Toxic and Carcinogenic residues long aeration (12-24 hours).
- Such as environmental concerns, and operational complexity can happens during the procedure.

**Validation:**

- Biological indicators with *Bacillus atrophaeus* spores are standard.

**3. Radiation Sterilization:**

In the sterilization process gamma and electron beam (E-beam) sterilization each of these are used for single-use, pre-packaged devices [14]. Gamma rays from the cobalt-60 and high-energy electrons damage the microbial DNA at a standard dose of 25 kGy [15].

**Advantages:**

- The advantages of the procedure is that, the gives the deep penetration and also no heat or moisture required to sterilization process.

**Limitations:**

- The long-term use of the sterilization process can degrade the polymers of the equipments [16].
- Procedure also requires the specialized facilities for the process to be completed.

**Validation:**

- The process incorporate mapping and sterility assurance level (SAL) testing to ensure the product safety and efficacy.

**4. Hydrogen Peroxide Plasma Sterilization**

This procedure gets continued at low-temperature. During the process with the help of hydrogen peroxide, plasma activation process generates reactive species that kill microorganisms [17].

**Advantages:**

- Devices which are heat sensitive are very much suitable for the procedure. This method does not leave any toxic residues after the process complitation.

**Limitations:**

- Limited penetration into long lumens
- Expensive equipment

**Validation:**

- *Geobacillus stearothermophilus* spores used for biological testing.

**Disinfection Methods**

1. **High-Level Disinfection (HLD)**

Semi critical devices such as, endoscopes and respiratory equipment went through the HLD disinfection process. Common agents like glutaraldehyde (2%), peracetic acid (0.2%), and hydrogen peroxide (7.5%) used during the process. Devices were first immersed in the glutaraldehyde solution for at least 20-45 minutes at room temperature, after that devices gets exposure to peracetic acid for 12-15 minutes in the reprocessing system. Devices like fiber optic instruments, gets disinfect with the hydrogen peroxide by immersion time of 30 minutes. Post-disinfection microbial cultures were performed to assess bacterial reduction.

**Advantages:**

- High level of bacterial spores gets eliminated during the process. [18].

**Limitations:**

- During this disinfection process agents used like glutaraldehyde may cause respiratory irritation and material degradation with the prolonged exposure.

**2. Intermediate-Level Disinfection**

This kind of disinfection process is usually performed for non-critical device, which contact intact skin. The agents used for the process were alcohol based disinfectants such as isopropyl alcohol, which were applied by using sterile wipes to disinfect thermometers and non-invasive medical devices and phenolic disinfectants, which used for disinfecting hospital furniture and non-critical surfaces.

**Advantages:**

- This method is effective against the most of the bacteria, viruses, and fungi.

**Limitations:**

- The method is effective against microorganisms but it did not affect the microspores, therefore it does not apply to such areas where spore disinfection is necessary.

**3. Low Level Disinfection**

A non-clinical and routine cleaning surface gets disinfected by the low-level disinfection procedure. Common agents used for the disinfection was Quaternary ammonium compounds ($QAC_S$), were applied to disinfect bed rails, wheelchairs, and blood pressure cuffs. Contact time and bacterial reduction efficacy were monitored.

**Advantages:**

- The method is effective against, most of the vegetative bacteria and some other viruses.

**Limitations:**

- However, against spores and mycobacterium this process remains ineffective. Microbial cultures were collected from the medical equipments before and after sterilization and disinfection process. After that swab samples were taken and incubated on tryptic soy agar (TSA) for the bacterial growth analysis [19].

**Result and Discussion**

The study reveals the effectiveness of the following methods:

**Sterilization Methods**

The result shows that all the sterilization procedures effectively eliminated microbial contamination from the medical devices. Yet, variations were observed in microbial efficacy, material compatibility, and operational feasibility.

**Autoclaving:**

Autoclaving also known as steam sterilization process effectively eliminate all the microbial organisms, including bacterial spores, as approved by the absence of microbial growth in biological indicator testing. *Geobacillus stearothermophilus* spores did not survive exposure at 121°C for at least 15 minutes or 134°C for 3-5 minutes. However, certain heat sensitive devices, like endoscopes and plastic based instruments, revels the structural degradation due to extended exposure to high temperatures.

**Ethylene Oxide (ETO) Sterilization**

ETO sterilization process effectively killed *Bacillus atrophaeus* spores, successfully demonstrate its suitability for the heat sensitive medical devices. However ETO gas requires extended aeration to make sure the safety, holding off the devices availability. Some of the materials retain the minimal ETO residues, which increase the necessity of the assessment of aeration times to comply with safety standards.

**Radiation Sterilization**

Gamma and electron sterilization completely eliminated microbial life from single use disposable devices. Not a single bacterial growth was observed in post irradiation culture tests. Yet, the polymer based materials presented slight discoloration and reduced mechanical strength after the frequent exposure to radiation, indicating possible material degradation over the time.

**Hydrogen Peroxide ($H_2O_2$) Plasma Sterilization**

$H_2O_2$ sterilization effectively inactivated *Geobacillus stearothermophilus* spores, with no microbial growth detected in post sterilization cultures. Contrary to ETO sterilization, no toxic residues were detected on medical devices. However the method shows limitation in sterilizing the long-lumen devices due to the restricted plasma penetration.

## Disinfection Methods

### High-Level Disinfection (HLD)

HLD, including glutaraldehyde and peracetic acid, extensively reduced the microbial contamination on semi-critical devices. No viable bacteria were detected after the immersion in 2% glutaraldehyde and peracetic acid for 12 minutes. However, the prolonged exposure to glutaraldehyde resulted in mild material degradation, and user reported respiratory irritation was noted, which indicates the occupational safety concerns.

### Intermediate and Low-Level Disinfection

Disinfectants like alcohol based and phenolic compounds effectively reduced the bacterial counts on non critical devices. However, the phenolic disinfectants reveal the reduced efficacy against bacterial spores and non-enveloped viruses. Quaternary ammonium compounds ($QAC_S$) provided acceptable low-level disinfection but were less effective against resistant pathogens such as *Clostridioides difficile* spores. **T**he effectiveness and a comparison of the methods are depicted in table 1, and it demonstrates the important discrepancies in stability and consistency.

**Table 1: Efficacy and Comparison of the Methods**

| Method | Microbial Efficacy | Material Compatibility | Residue Concern | Processing Time |
|---|---|---|---|---|
| **Steam Sterilization** | High | All poor for heat sensitive devices | None | Fast |
| **Ethylene Oxide** | High | Excellent for heat sensitive items | Require aeration | Slow |
| **Radiation** | High | May degrade some polymers | None | Fast |
| **$H_2O_2$ Sterilization** | High | Good for sensitive materials | None | Fast |
| **High-Level disinfection** | High | Moderate to good | Minimal residue | Fast |
| **Intermediate disinfection** | Moderate | Good | Minimal residue | Fast |
| **Low-Level disinfection** | Low-Moderate | Excellent | Minimal residue | Fast |

## Implications for the Clinical Practice

The result highlighted the importance of selecting suitable sterilization and disinfection procedure based on the medical device classification. Some devices like critical ones are required sterilization to make sure to complete microbial eradication, while devices like semi-critical and non- critical ones are benefited from high and intermediate-level disinfection.

## Conclusion

Sterilization and Disinfection are the essential for ensuring the safety effectiveness of the medical equipments. The procedure selection for the sterilization and disinfection depends on the device type, material, and microbial risk. Steam sterilization, ETO, radiation, and hydrogen peroxide plasma, such methods are common and offer the varying benefits and limitations. Autoclaving is very effective method, but it is unsuitable for heat-sensitive devices, while ETO is suitable for the delicate materials, yet it poses the toxicity concerns. Methods like radiation may degrade the materials over time and hydrogen peroxide plasma has very limited penetration. Disinfection methods are crucial for semi-critical and non-critical devices but it may lead to the material damage and limited efficacy against resistant organisms. Recent challenges like microbial resistance, material compatibility, toxic residues, and cost barriers, can be solved through the current methods. Therefore, precise selection and enhancing of the sterilization and disinfection methods are crucial for balancing the efficacy, safety, and material integrity in modern healthcare practice.

## References


1. Triggiano, Francesco, Enrico Veschetti, Federica Veneri, Maria Teresa Montagna, and Osvalda De Giglio. "Best practices for disinfection in dental settings: insights from Italian and European regulations." ANNALI DI IGIENE MEDICINA PREVENTIVA E DI COMUNITÀ 37, no. 2 (2025): 292-301.
2. Chu, Zhengdao, Yukai Zhou, Saite Li, Qiaosheng Xu, and Lijia Pan. "Implantable Medical Electronic Devices: Sensing Mechanisms, Communication Methods, and the Biodegradable Future." Applied Sciences 15, no. 13 (2025): 7599.
3. Steinecker, Heidi W. "Challenges and Strategies of Implementing the World Health Organization Infection Control Protocols in Rural Ugandan Hospitals." PhD diss., The Medical College of Wisconsin, 2025.
4. Xiong, Juan, Wei Jiang, Wei Wan, Li Zuo, Ping Tu, and Dong Xia Rao. "Improving precision instrument cleaning with a quality control module: implementation and outcomes." *Frontiers in Public Health* 13 (2025): 1553113.
5. Zhu, Yuting, Wendy Moyle, Min Hong, and Kean Aw. "From Sensors to Care: How Robotic Skin Is Transforming Modern Healthcare—A Mini Review." Sensors 25, no. 9 (2025): 2895.
6. Zaki, Mohammed Zaki Raiq, Zeina Ahmed Mohsen, Taha Ghassan Adnan, Yousif Dhyeaa Saeed, and Abdullah Hassan Ali. Sterilization and Clean Design in Medical Devices: Principles, Standards, and Innovations. Book Rivers, 2025.
7. AlSaiari, Abdullah Khalid Amer, Mohammad S. Alonazi, Nasser Muneer Alotaibi, Hamad AlQahtani, Waleed Masoud Alotaibi, Awatef Sliman Saleh Al Yhyha, Aqilah Aldarorah et al. "Bioengineering Innovations in Global Dental Infection Control: Applications and Adaptations in Clinical Settings." International Dental Journal 75, no. 3 (2025): 2222-2238.
8. Garvey, Mary, Terra A. Kremer, and Neil J. Rowan. "Efficacy of cleaning, disinfection, and sterilization modalities for addressing infectious drug-resistant fungi: a review." Journal of Applied Microbiology 136, no. 1 (2025): lxaf005.

9. Tuluhongtayi, Yeerzati, Wenjun He, Kun Cai, Weifang Han, Sheng Zhang, Jun Liu, Wenwen Lei, Zongxing Zhang, Jiancheng Qi, and Guizhen Wu. "Vaporized hydrogen peroxide sterilization of powered air-purifying respirators: Efficacy and safety assessment." Current Research in Biotechnology (2025): 100312.

10. Santoro, Angelo, Andrea Voto, Luigi Fortino, Raffaella Guida, Carolina Laudisio, Mariarosaria Cillo, and Anna Maria D'Ursi. "Bone defect treatment in regenerative medicine: exploring natural and synthetic bone substitutes." International Journal of Molecular Sciences 26, no. 7 (2025): 3085.

11. Tuluhongtayi, Yeerzati, Wenjun He, Kun Cai, Weifang Han, Sheng Zhang, Jun Liu, Wenwen Lei, Zongxing Zhang, Jiancheng Qi, and Guizhen Wu. "Vaporized hydrogen peroxide sterilization of powered air-purifying respirators: Efficacy and safety assessment." Current Research in Biotechnology (2025): 100312.

12. Menon, Lakshmi, Dhruv Sanjanwala, Shivansh Sharma, Ratnesh Jain, and Prajakta Dandekar. "Sterilizing bioinks: Understanding the impact of techniques on 3D bioprinting materials." Bioprinting 48 (2025): e00399.

13. Garvey, Mary, Terra A. Kremer, and Neil J. Rowan. "Efficacy of cleaning, disinfection, and sterilization modalities for addressing infectious drug-resistant fungi: a review." Journal of Applied Microbiology 136, no. 1 (2025): lxaf005.

14. Tartaro Bujak, Ivana, Željka Knežević, and Marija Majer. "Radiation processing for public health: Croatia's contribution to food safety and sterilisation practices." Arhiv za higijenu rada i toksikologiju 76, no. 1 (2025): 16-23.

15. Wu, G., and K. Zhang. Application of Gamma Irradiation for the Preparation of Pseudocapacitive Supercapacitor Materials. No. IAEA-CN-332/817. 2025.

16. Krieghoff, Jan, Gaby Gotzmann, Tobias Teichmann, and Michaela Schulz-Siegmund. "How to sterilize biodegradable polymers? An in-depth characterization of effects of low energy electron beam irradiation (LEEI) and gamma irradiation on the molecular weight of poly (lactide-co-glycolide) films." International Journal of Pharmaceutics (2025): 125684.

17. Wei, Min, Yuyan Sun, Yijin Zhu, Yujia Huo, Chongyu Zhong, Qiaoyun Wei, and Yueyue Fei. "Atmospheric Pressure Cold Plasma Treatment: A Potential New Strategy for Sterilizing and Purifying Water Quality in Aquaculture." Yuyan and Zhu, Yijin and Huo, Yujia and Zhong, Chongyu and Wei, Qiaoyun and Fei, Yueyue, Atmospheric Pressure Cold Plasma Treatment: A Potential New Strategy for Sterilizing and Purifying Water Quality in Aquaculture.

18. Silva, M. P., C. A. Pereira, J. C. Junqueira, and A. O. C. Jorge. "Methods of destroying bacterial spores." Microbial pathogens and strategies for combating them: science, technology and education 1 (2013): 490-496.

19. Firesbhat, Atsedewoyn, Abiye Tigabu, Birhanemeskel Tegene, and Baye Gelaw. "Bacterial profile of high-touch surfaces, leftover drugs and antiseptics together with their antimicrobial susceptibility patterns at University of Gondar Comprehensive Specialized Hospital, Northwest Ethiopia." BMC microbiology 21, no. 1 (2021): 309.