Microbiological Evaluation of the Low-Temperature Sterilization Method Operating with Hydronium

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INTRODUCTION–PURPOSE:

Low-temperature sterilization methods are sterilization methods frequently used in Central Sterilization Units (CSUs), but depending on the method used, they may have disadvantages such as limitations in lumen diameter and length or toxicity. This study was conducted to clinically evaluate the HRF 3000 HdrOZON (Teknomar, Türkiye) device, which is claimed to eliminate these disadvantages and performs sterilization using Hydronium ion technology obtained by the combined use of Hydrogen Peroxide and Ozone gases.

MATERIALS–METHOD:

This study was conducted in the Teknomar R&D laboratory. The sterilization process with HRF 3000 hdrOZONE is carried out through 8 consecutive stages. After the chamber temperature reaches 44 °C:

1- Vacuum phase: Bringing the sterilization chamber to -600, -900 mBar vacuum,
2- Injection phase: Vaporization of 5-10-15 cc 60% H2O2 concentration and injection into the sterilization chamber,
3- Diffusion phase: Diffusion of hydrogen peroxide into the materials to be sterilized,
4- Taking oxygen into the system, ozonating it and delivering it to the chamber,
5- Adsorption of hydrogen peroxide and ozone onto the materials to be sterilized by forming a heavy molecule,
6- Diffusion of Hydronium into the sterilization chamber,
7- Plasma phase: Performing HRF COLD PLASMA under -300/-700 mBar atmospheric vacuum,
8- Ventilation-Aeration phase: return to normal atmospheric pressure.

Polytetrafluoroethylene (PTFE) tubes were used as the challenging test system (PCD) in the study. The tested length (mm) and diameter (mm) measurements were 850-1, 1200-2, 500-0.7, 900-0.4, 7500-2, 10000-2, 15000-2, respectively. BIONOVA brand bacterial spore strips with a D-value of 10 sec containing 10^6 Geobacillus sterothermophilus were placed at the closed end of the challenging test systems and packaged with 4A brand TYVEK. All test systems were placed in different localizations inside the chamber in each cycle and tested as full cycle and half cycle. Each test system was repeated three times, the strips were inoculated into Tryptic Soy liquid medium and incubated at 55 °C for 7 days, and the logarithmic reduction factor (LRF) (LRF = log10 [control] – log10 [test]) was calculated.

FINDINGS:

In all test systems and in all cycles, the reduction factor was calculated as 8 log compared to the positive control.

CONCLUSION:

According to our findings, the HRF 300 HdrOZONE device meets the microbiological requirements of a l ow-temperature sterilization method in accordance with the ISO 14937 standard.

Keywords: Low-temperature sterilization, hydronium, hydrogen peroxide, ozone.