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Sterilization of Medical Devices Using Low Pressure N_2/O_2 Mixed Gas Plasma

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Potential sterilization of medical devices is investigated using a specific plasma process. The inactivating medium of the microorganisms is the flowing afterglow of a reduced-pressure N_2-O_2 discharge, which provides, as the main biocidal agent photons over a broad ultraviolet (UV) wavelength range. The flowing afterglow is considered less damaging to medical devices than the discharge itself.

Working at gas pressures in the 400-700 Pa range ensures, through species diffusion the uniform filling of large volume chambers with the species out flowing from the discharge possibly allowing batch processing within them. As a rule bacterial endospores are used as a biological indicator (BI) to validate sterilization processes. Under the present operating conditions *Geobacillus stearothermophilus* ATCC 7953 is found to be the most resistant one and is therefore utilized as BI.

This editorial paper describes the main experimental results concerning the operation and characterization of this sterilizer updating and completing some of the author's previous papers. It uses modeling results as guidelines, which are particularly useful when the corresponding experimental data are not yet available, hopefully leading to more insight into this plasma afterglow system. The species flowing out of the N_2/O_2 discharge can be divided into two groups depending on the time elapsed after they left the discharge zone as they move toward the chamber, namely the early afterglow and the late afterglow.

The early flowing afterglow from a pure N_2 discharge is known to be comprised of N_2^+ and N_4^+ ions. In the present N_2/O_2 mixture discharge, NO^+ ions are additionally generated with a lifetime that extends over a longer period than that of the nitrogen molecular ions. The author supposes that the disappearance of the NO^+ ions marks the end of the early afterglow regime, thereby stressing intent to work in an ion-free process chamber to minimize damage to medical devices. Therefore, operating conditions should be set such that the sterilizer chamber is predominantly filled by N and O atoms possibly together with long-lived metastable-state O_2 singlet molecules.

Various aspect related to the observed survival curves are examined (ISO 11138-1); the actual existence of two phases in the inactivation rate the notion of UV irradiation dose and its implications the UV photon best wavelength range in terms of inactivation efficiency the influence of substrate temperature and the reduction of UV intensity through surface recombination of N and O atoms on the object being processed. To preserve their on-shelf sterility medical devices are sealed/wrapped in packaging material. Porous packaging materials utilized in conventional sterilization systems (where medical devices are packaged before being subjected to sterilization) were tested and found inadequate for the N_2-O_2 after glow system in contrast to a (non-porous) polyolefin polymer. Because the latter is non-porous its corresponding pouch must be kept unsealed until the end of the process. Even though it is unsealed, but because the opening is very small the O_2 metastable–state molecules are expected to be strongly quenched by the pouch material as they try to enter it and as a result, only N and O atoms together with UV photons, are significantly present within it. Therefore by examining a given process under pouch and no-pouch conditions, it is possible to determine what are the inactivating agents operating:

(1) when packaged, these are predominantly UV photons

(2) when unpackaged, O_2 metastable molecules together with UV photons can be acting

(3) comparing the inactivation efficiency under both packaged and unpackaged conditions allows the determination of the relative contribution of UV photons (if any) and O_2 metastable-state molecules. Such a method is applied to pyrogenic molecules and to the enzymatic activity of lysozyme proteins once exposed to the N_2-O_2 flowing afterglow. Finally the activity of the infectious prion protein is shown to be reduced when exposed to the present flowing afterglow, as demonstrated by both *in vitro* and *in vivo* experiments.

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