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Future prospect of gas plasma sterilization method and how the regulatory agencies consider about gas plasma sterilization

ガスプラズマ滅菌法の実用化の展望と厚労省の考え方

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中央大学理工学部　〒112-0003 東京都文京区春日 1-13-27

The major factors included in gas plasma sterilization are reported to be radicals, metastable ions, UV, VUV and so on. These are the same as those currently conducted sterilization procedures. For example, major chemical sterilant of gamma-ray sterilization is OH radical and OH radical attacked to DNA/RNA bases produced OH derivatives of DNA/RNA bases such as 8OH Guanine and so on. These OH derived DNA/RNA bases fall into failure of hydrogen bonding formation between Adenine to Thimine, Adenine to Urasil and Guanine to Cytosine, so it resulted in failure of genetic codes and cell death. This process is quite the same as oxygen gas plasma sterilization. So what differs between gamma-ray sterilization and oxygen gas plasma sterilization? The major difference of both is penetration depth. The former is much greater. For sterilization of the contaminants of medical devices, bioburden, penetration depth is enough to 10-20 nm, which scale is identical to that of gas plasma exposure. The material and functional compatibility of the sterilized medical devices are hard to maintain if penetration depth is more than 10-20 nm. In that means, currently performing sterilization procedures are hard to maintain the scope of Japan Pharmaceutical Low. Therefore, it has been searched for the alternative sterilization procedure to simultaneously attain both sterility assurance level (SAL) of 10^{-6} and material/functional compatibility. The sterilization procedure to satisfy both SAL of 10^{-6} and material/functional compatibility is only gas plasma sterilization. On March 31 2011, this year, gas plasma sterilization was officially presented in Japan Gazette and gas plasma sterilization was officially noticed from the Ministry of Health and Labor Welfare. From now on it is hoped that gas plasma sterilization is going to be practically applied and utilized in the world. In this presentation, future prospect of gas plasma

sterilization utility and what Regulatory agencies are hoped for the future of gas plasma sterilization procedures.