MIURA

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Developing innovative new hybrid processing-based sterilization technologies using hydrogen peroxide and ozone gas —Efficient processing of poisonous substances such as endotoxins for which inactivation is difficult

MIURA CO.,LTD. (Head Office: Matsuyama, Ehime; President & CEO: MIYAUCHI Daisuke), a company with extensive experience in washers and sterilizers for commercial and medical use, announces that <u>it is developing an innovative "next-</u> <u>generation sterilization system" capable of efficiently sterilizing and eliminating</u> <u>bacterial pathogens that are dangerous to human life, such as the novel</u> <u>coronavirus and drug-resistant bacteria.</u>

[Powerful new sterilization techniques that meet the demands of cuttingedge medicine]

Sterilization systems currently in development are fitted with <u>new sterilization</u> <u>technology</u> ("the Technology") that adds small amounts of ozone gas to hydrogen peroxide gas to induce an accelerated oxidation process, and enhances sterilization. The effects of the Technology are also being confirmed in research^{*2} by the Japan Agency for Medical Research and Development^{*1}.

[Effects of the Technology]

(1) Reduced health hazards for operators and patients

→ Because the amount of hydrogen peroxide used can be reduced to one-third of that of conventional methods, the effects of sterilization on subjects (such as residual chemical substances, poisoning due to residual chemical substances) can be kept to a minimum. This promises to reduce health hazards for operators and patients.

(2) Effective inactivation of endotoxins

→ Inactivates 99.9% or more of endotoxins, which could not be sufficiently inactivated using conventional sterilization methods.

[Importance of endotoxin inactivation]

What are endotoxins?

Primarily, endotoxins are pyrogenic toxins contained in dead bacteria. When they enter the blood through medical instruments and equipment, they cause problems such as the rapid onset of fever, septicemia, or multiple organ failure. Although these dangers are widely recognized, it is known that the sterilization technologies currently deployed in medical institutions cannot achieve sufficient inactivation^{*3}.

[Anticipated effects of endotoxin inactivation]

(1) Risk mitigation in high-risk surgical operations such as those involving contact with cerebrospinal fluid that require particularly clean, sterile conditions

 \rightarrow Suppressing post-operative fever due to endotoxin contamination.

(2) Improved precision in the field of regenerative medicine

- → Hyperplasia of cells caused by minute quantities of endotoxins can be suppressed, allowing cell culture to proceed in a stable manner.
- (3) Effect on assisted reproductive technology (infertility treatments for those with intractable infertility)
 - → Suppresses significant declines in the rate of pregnancies maintained due to endotoxin contamination of culture solution.

Going forward, high-level endotoxin inactivation will become essential with the development of advanced medicine such as regenerative medicine and assisted reproductive technology, fields that are predicted to grow in the future.

[Future growth supported by the Technology]

In addition to endotoxins, the Technology has been found to be experimentally effective in breaking down DNA and RNA, and evaluation of its use is underway in a variety of scenarios as follows.

Medical fields

The Technology is anticipated to allow processing at lower concentrations and with greater efficiency than conventional methods (where ozone and hydrogen peroxide are used independently) for inactivation of the prions that are thought to be the cause of Creutzfeldt-Jakob disease (a human form of bovine spongiform encephalopathy), and for the environmental cleaning and disinfection that have been found to be a significant risk with the current novel coronavirus, and research is progressing.

Environmental fields

MIURA is working to break down and inactivate drug-resistant bacteria (bacteria that is resistant to antibiotics) at a genetic level and reduce the spread of bacterial environments.

• Water treatment fields

Because the Technology also shows promise as a depolymerization technique for use with organic matter, it is also being considered for use in the water treatment marketplace, which makes use of processing technologies for organic matter that does not decompose easily.

MIURA will contribute to medicine in Japan and around the world through commercialization of sterilization systems that use new sterilization technologies.

• Market predictions anticipated for adoption of the rechnology			
	2020	2030	2050
World	26 billion yen	36.9 billion yen	80 billion yen
Japan	4.98 billion yen	6.55 billion yen	7.48 billion yen

[Reference materials]

▼ Market predictions anticipated for adoption of the Technology

* By MIURA's own research

*1 Japan Agency for Medical Research and Development

An organization that offers research assistance and environmental maintenance to universities and research institutions (Abbreviation: AMED, Location: Chiyoda-ku, Tokyo, Director: Makoto Suematsu). Performs research for the medical research and development promotion project such as Drug development promotion research project: Collaborative public and private-sector research to promote the practical use of pharmaceuticals and medical devices^{*2}.

*2 Drug development promotion research project: Collaborative public and private-sector research to promote the practical use of pharmaceuticals and medical devices

In 2014, selected as "Ministry of Health, Labour and Welfare Research" by the Ministry of Health, Labour and Welfare, and put into practice at AMED from 2015. In order to accelerate the clinical use of pharmaceutical products, the administration, which evaluates technical requirements and evaluation methods for development and approval applications of pharmaceuticals and medical devices, the industries that have a wealth of experience in product development, and the academic institutions that perform fundamental research that supports the technical requirements work in a collaborative research framework, aiming to collect basic, fundamental data in order to create guidelines for technical requirements and establish official methods of assessment.

*3 Reference: Kazunari HOSOBUCHI and Kenichi TANAMOTO, "Inactivation of dry endotoxin by several sterilization methods", Tokyo Metropolitan Industrial Technology Research Institute Bulletin of Study No.2 (1999)

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