High level disinfection of transvaginal probes in IVF and similar settings

Critical Summary

- There are several factors to consider when selecting a high level disinfectant for transvaginal probes used for oocyte retrieval and other IVF applications.
- IVF settings are complex, requiring specific processes to ensure safe handling of sensitive embryos and oocytes.
- Hydrogen peroxide is preferred for environments where toxicity, sensitization and irritation are of significant concern.

Factors to consider when assessing suitability of HLD methods

When selecting a high level disinfection method for IVF applications, special attention should be given to toxicity risks. The points below summarise the case for hydrogen peroxide as a preferred disinfectant for IVF applications.

- In the United States, CDC guidelines recommend hydrogen peroxide disinfection for retrieved cells based on its lesser toxicity compared to other disinfectants.

> *"High-level disinfection with a product (e.g., hydrogen peroxide) that is not toxic to staff, patients, probes, and retrieved cells should be used until the effectiveness of alternative procedures against microbes of importance at the cavitary site is demonstrated by well-designed experimental scientific studies."*[1]

- Studies on a range of disinfectants conducted at FDA's Office of Science and Technology showed that there is a several-hundred fold difference in the relative toxicity of various disinfecting substances. Hydrogen peroxide was classified in the lowest risk group with the 50% toxic concentration (TC_{50}) being greater than 1 mM (34 µg/mL).[2]
- Most human cells are naturally exposed to some level of hydrogen peroxide and on contact with mammalian tissues, hydrogen peroxide is immediately broken down to oxygen and water by the action of catalases.[3,4] The highest catalase activities are observed in highly vascularised tissues including mucous membranes. Hydrogen peroxide is produced naturally by commensal *lactobacilli* in the vagina and even plays an antibacterial role by preventing growth of bacterial species associated with bacterial vaginosis.[5]
- The CDC requires that high level disinfection (HLD) is performed during the reprocessing of transvaginal ultrasound transducers. While it is clear that hydrogen peroxide has many favourable characteristics for disinfection in IVF applications, alternative HLD methods are well known to cause a range of toxic, irritating and sensitizing effects.
- Glutaraldehyde (GTA) and *ortho*-phthalaldehyde (OPA) have been shown to be absorbed by various plastics and to cause cytoxic effects even after the plastics are washed. There is cause for concern that GTA and OPA can be absorbed and consequently released from plastic medical devices such as ultrasound transducers, even after rinsing.[6]

- Contact of GTA sterilized surgical instruments with culture media has been shown to disrupt embryonic development in a murine embryonic culture system.[7]

- Many case reports have been published where workers and patients have experienced respiratory problems, anaphylaxis, skin reactivity, and systemic antibody production with use of OPA.[8-12] OPA causes acute inflammation, is a dermal and respiratory sensitizer in mice and has also been shown to be a dermal irritant at working concentrations.[13-15]

- Regular exposure to sterilants including GTA, but not hydrogen peroxide, has been linked to a 2-fold increased risk of late-spontaneous abortion in pregnant healthcare workers.[16]

- Given the risks, a review concluded there was a need to move toward a GTA free sonography environment.[17]

In summary, hydrogen peroxide based HLD is preferred for the disinfection of transducers where toxicity, sensitization and irritation are of significant concern, particularly in procedures such as oocyte retrieval.

trophon®

trophon is a high-level disinfection (HLD) device specifically designed for the disinfection of ultrasound transducers. trophon is ideal for applications where toxicity is a major concern, particularly for procedures such as oocyte retrieval. The trophon family includes the trophon EPR and trophon2 devices, which share the same core technology of sonically activated hydrogen peroxide.

trophon enhances safety

Nanosonics has conducted a safety assessment of peroxide residues on transducers disinfected by the trophon in accordance with International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1. The safety assessment considers the worst case scenario including use of 50% H_2O_2 (rather than the standard 35%), the use of maximum dosage, the use of old and worn transducers with surface imperfections, the use of 5 serial disinfection cycles without any wiping (contravening the instructions for use) and assumes that a probe cover and coupling gel are not used. Under these worst case conditions, the residuals of hydrogen peroxide were found to present negligible biocompatibility risk based on an extensive literature search, even with chronic exposure. In real-world use, transducers are used with both gel and a probe cover meaning that normal clinical exposures would be exceedingly low.

In comparison to manual HLD methods that use glutaraldehyde (GTA) or *ortho*-phthlaldehyde (OPA), trophon reduces the risk of exposure to toxic disinfectant chemistries for retrieved cells, patients and staff. At the end of each cycle, the hydrogen peroxide disinfectant is broken down into water and oxygen.

Moreover, trophon has been shown to leave residual levels of hydrogen peroxide which are below thresholds for toxicity. The fact that hydrogen peroxide is a naturally occurring substance in the body and that it is rapidly degraded in tissues and mucous makes it a favourable choice for HLD of transducers used in IVF applications. The device is also fully automated, reducing the risk of operator error compared to manual methods.

In standard healthcare settings, trophon can be used in the patient environment with a dirty to clean workflow. IVF settings are complex, requiring specific processes to ensure safe handling of sensitive embryos and oocytes. It is therefore recommended reprocessing areas are separated from areas where embryos and oocytes are handled.

Contact us today for your specific needs on point-of-care reprocessing, understanding when to HLD or for an educational session at your facility.

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Nanosonics Limited 14 Mars Road, Lane Cove, NSW 2066, Australia, T: +61 2 8063 1600 E: info@nanosonics.com.au www.nanosonics.com.au
USA & Canada. Nanosonics Inc. 7205 E 87th Street, Indianapolis, IN 46256, USA T: 1-844-TROPHON 1-844-TROPHON 1-844-876-7466 E: info@trophon.com W: www.trophon.us

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