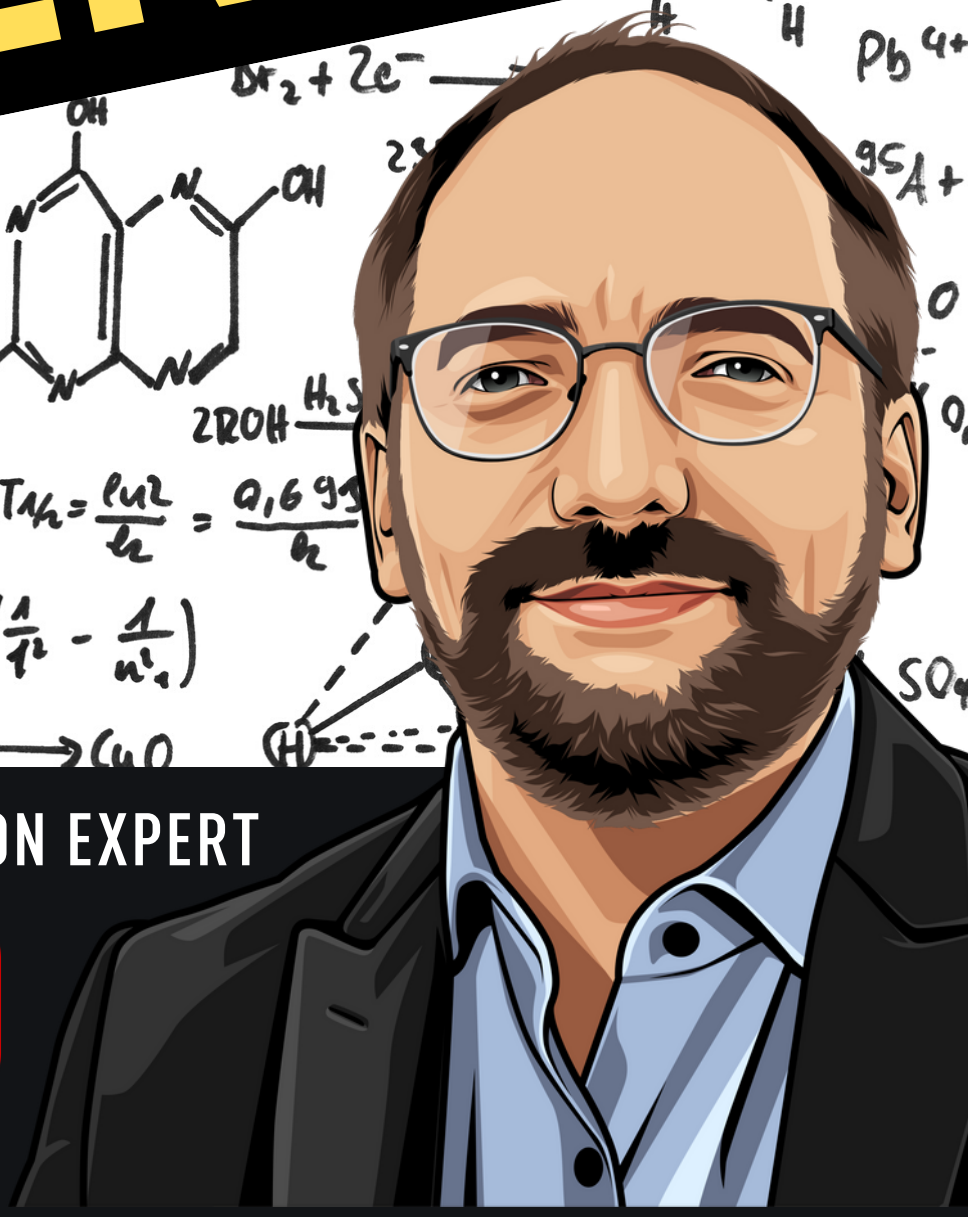
HOW DO I KNOW IT'S STERILE?



LOW TEMP STERILIZATION EXPERT

BEYOND CLEAN

Jean-Luc Lemyre | Senior Manager R&D | Stryker

Beyond Clean Low Temp Sterilization Expert ™:

HOW DO I KNOW IT'S STERILE?

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Sterilization of reusable medical devices is a great thing to prevent patient infection, but how do we know a medical device is sterile? Well, the sterility of medical devices cannot be directly verified prior to clinical use. For this reason, sterilization processes themselves must be validated. The goal of this validation is to confirm the success and repeatability of the sterilization process when performed within validated parameters. These include microbial loads, types of devices, load configurations, sterile packaging, load temperature, etc. In addition to this validation, users routinely monitor the sterilization process by confirming adequate sterilizer cycle parameters (e.g. pressure, time, H_2O_2 concentration) and by using process indicators (BI, CI, PCD). Does this all guarantee that we get sterile devices? Not exactly.

Sterility is not an absolute certainty; it is a probability. A sterilization process reduces the number of viable microorganisms on medical devices. We can even measure it! For H_2O_2 sterilization, this is typically measured in a laboratory by using half of the sterilization cycle, while employing operating conditions that are deemed the most challenging. These test conditions reflect the validated process parameters. The measured reduction of microorganisms at half-cycle can be used to calculate the odds of getting a non-sterile device with the full cycle. The FDA requirement is that no more than one in a million devices sterilized may have a viable microorganism remaining. This specific threshold corresponds to the Sterility Assurance Level (SAL) of 10-6! To consistently achieve this sterility assurance level during routine sterilization, it is essential that medical devices are processed within the validated limits and according to the indications provided by the manufacturers of <u>all</u> devices involved: the medical devices being sterilized, the sterilizer, the sterile packaging, the process indicators. In other words, to prevent patient infection... follow the IFUs!

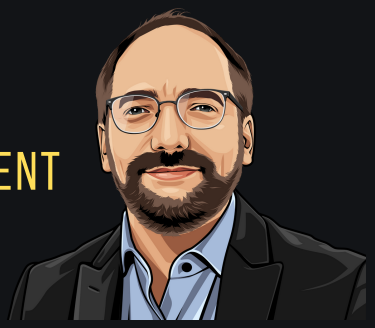
Have more low temp sterilization questions? Contact Jean-Luc at: jeanluc.lemyre@stryker.com

Beyond Clean Low Temp Sterilization Expert™ Biography:

JEAN-LUC LEMYRE

SENIOR MANAGER RESEARCH & DEVELOPMENT

stryker



Jean-Luc is passionate about science and innovation and has been involved in R&D for two decades, ranging from fundamental academic research to product development. He joined TSO3 in 2016 where he was introduced to low-temperature sterilization of medical devices using hydrogen peroxide and ozone. Today, Jean-Luc is a Senior Manager of R&D at Stryker following the acquisition of TSO3. In this role, he leads a team of scientists and engineers dedicated to innovating for the benefit of sterile processing professionals. During his career, Jean-Luc has been involved in several product improvements along with the associated regulatory clearances. He is also an active member of standards development committees with AAMI and ISO.

Before discovering his passion for sterile processing, he started his career doing R&D in the field of personal protective equipment. He has a PhD in chemistry from Université Laval in the beautiful Québec City, where he still lives with his family.

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