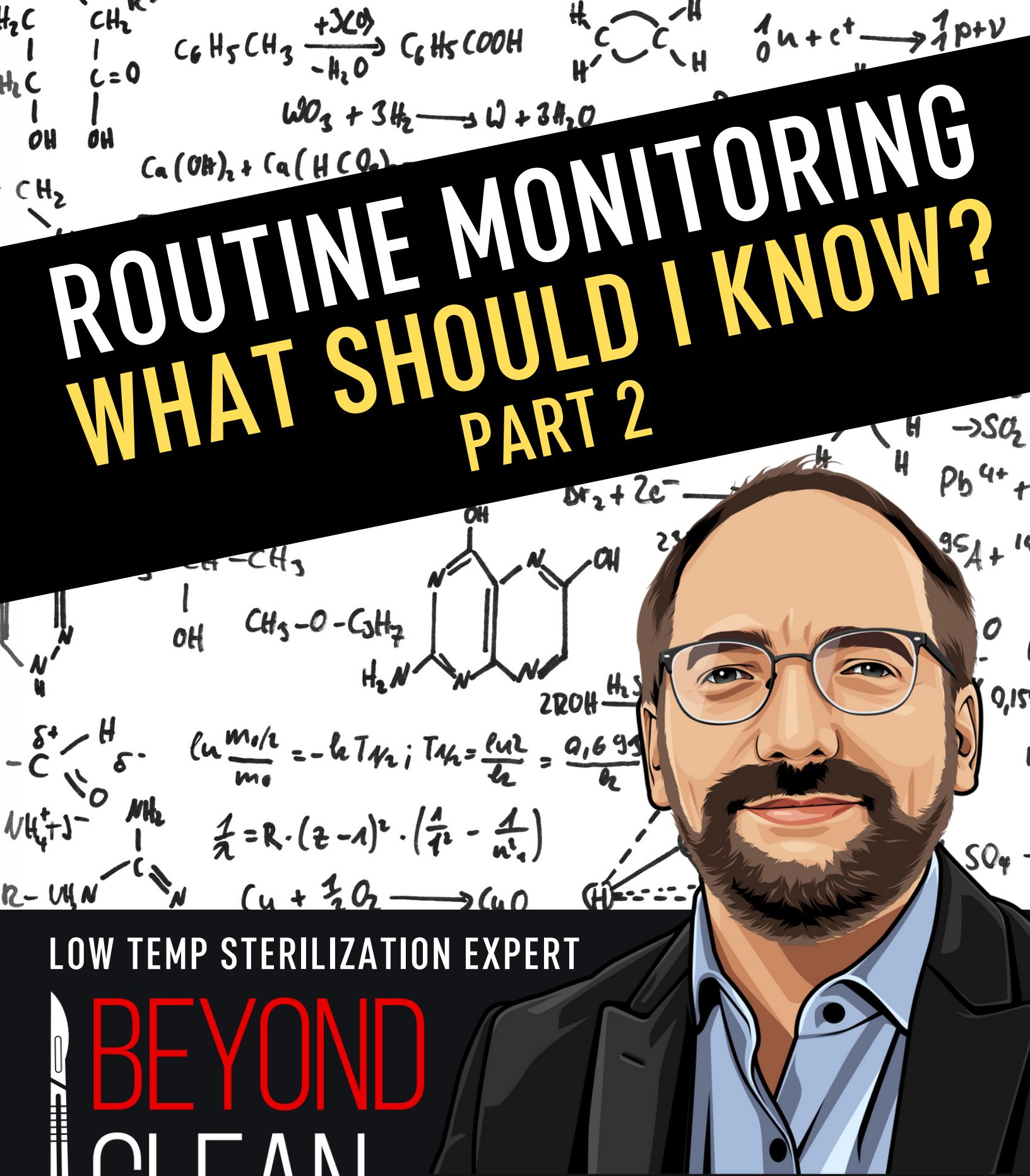
ROUTINE MONITORING
WHAT SHOULD I KNOW?
PART 2



LOW TEMP STERILIZATION EXPERT

BEYOND CLEAN

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Beyond Clean Low Temp Sterilization Expert ™:

ROUTINE MONITORING WHAT SHOULD I KNOW? - PART 2

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Continuing from our last post around routine monitoring, let's jump into biological indicators (BI) and process challenge devices (PCD). BIs contain a microorganism resistant to an intended sterilization cycle and are used to confirm its lethality. For terminal sterilization using H_2O_2, it always contains at least a million viable spores of Geobacillus stearothermophilus. The BI result tells us if the indicator was exposed to conditions sufficient to kill all the spores it contains. Combined with our CI results, we now know two things: the sterilant was present at the CI locations and it was able to kill all organisms in the BI. But what about scopes or hard-to-reach places? Was the cycle capable of getting its deadly sterilant everywhere it needed to go? The BI could have been easier to sterilize than some medical devices, and this is where the PCD completes the picture.

PCDs for H_2O_2 processes contain a BI and are designed to mimic the resistance to the sterilization process of the most challenging instrument routinely processed. They emulate the toughest maze our sterilant could have to solve, and thus confirm the presence of adequate cycle conditions to sterilize even the most challenging devices. However, knowing that adequate cycle conditions were present is still insufficient to guarantee devices' sterility, as it also relies on compliance to all previous processing steps (e.g. cleaning), as described in the validated IFUs. Nonetheless, the use of an appropriate PCD containing a BI is a powerful tool for detecting sterilization failure. Even though a PCD should be used at least daily, it is best used in every load.

Altogether, the combination of rigorous validation of the sterilizer cycles, compliance to the validated IFUs and routine monitoring of the sterilization cycle can provide confidence that a sterilization process has successfully rendered a given instrument sterile.

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

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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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