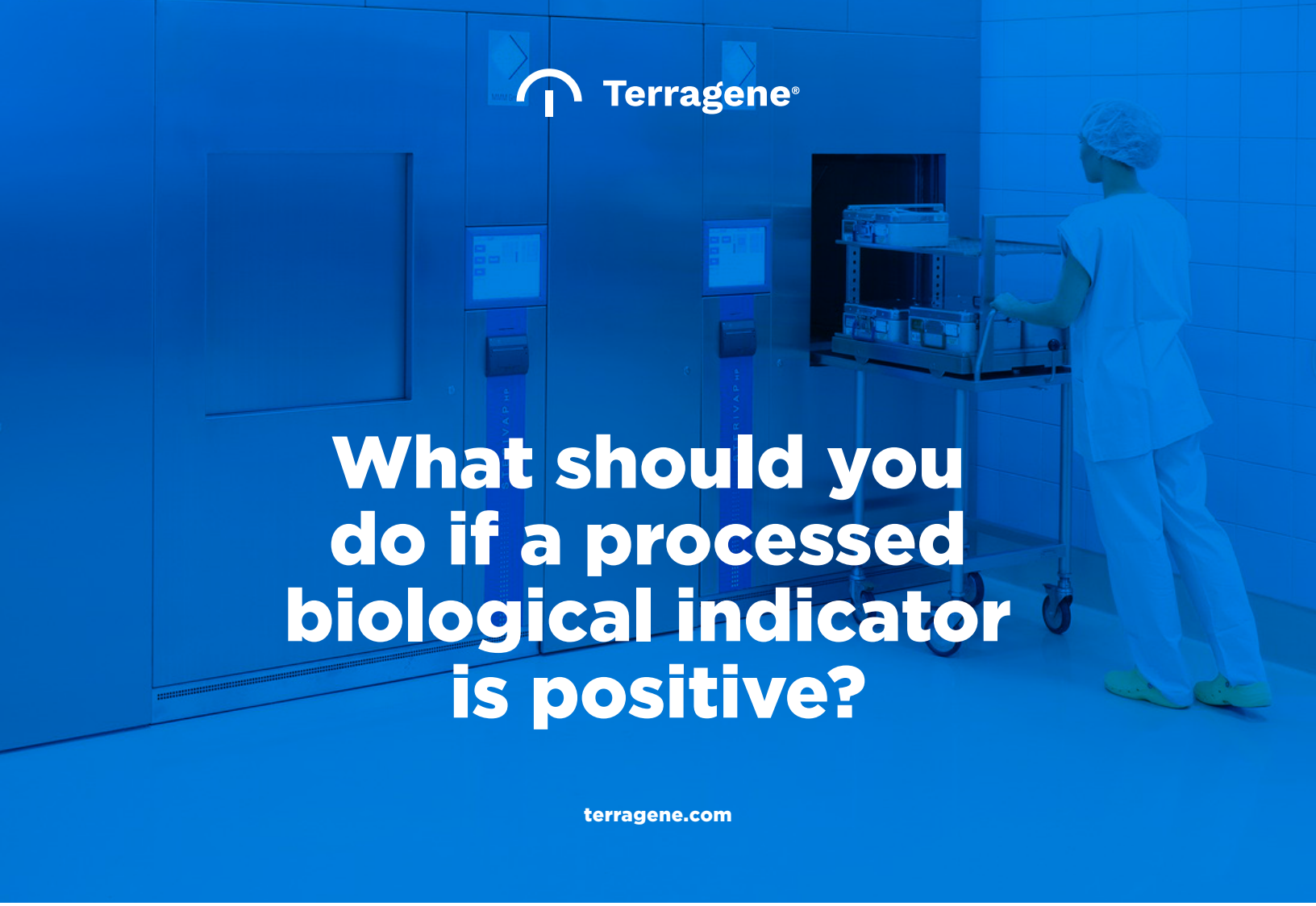

Terragene®

What should you do if a processed biological indicator is positive?

terragene.com

STERILIZATION CYCLE

Verify Cycle Information

- Check the sterilizer display/screen and printout to verify if everything is under control.
- Review and evaluate if there were any undesirable events or interruptions during the cycle.
- Compare cycle parameters against a validated cycle to ensure temperatures, pressure, exposure times, F0 (steam sterilization process), humidity (EO sterilization process), or chemical agent concentration (EO, H2O2, or LTSF sterilization processes) are suitable.
- Check if all (visible)chemical indicator used are correctly processed in the cycle.
- Verify the result of a positive control.

Load preparation, packing and handling

- Investigate potential errors in this procedure with the sterilization technician.
- Check load storage before processing was at the conditions set by standard operating procedures (SOPs).
- Verify that the packaging material is compatible with the sterilization process.
- Check the assembly of the processed packages.
- Verify that the sterilizer is not overloaded. The loading volume must be less than or equal to that recommended by the sterilizer manufacturer.
- Confirm that load location within the chamber met SOPs.

STERILIZER EQUIPMENT

Sterilizer Performance

- Verify that condensate traps on the jacket and chamber are clean (Steam and LTSF sterilizers).
- Check that the strainers on steam supply and condensate piping are clean (Steam and LTSF sterilizers).
- Use load probes to verify that the temperature profile in the chamber is within proper parameters during exposure.
- Ensure that the sterilizer cycle timer accurately meets factory specifications.
- Run a Bowie-Dick test on prevacuum steam sterilizers to detect inadequate air removal and/or steam penetration from the chamber.
- If available, perform a leak test cycle and compare the results to previous tests recorded.
- Verify the calibration registers.

Quality of the sterilizing agent

- Verify that the sterilizing agent is within its useful life (EO, H2O2 and LTSF).
- If the chemical agent container has a chemical exposure indicator (EO, H2O2 and LTSF processes), verify that it is the initial color.
- Check for water priming at the boiler, faulty traps, or a faulty steam condensate return system, which can create excessive condensate in the steam.
- Ensure that the steam isn't super-heated by verifying the pressure and temperature in the sterilizer jacket is lower than in the sterilizer chamber.

BIOLOGICAL INDICATORS

Biological Indicator recommended use

- Verify that the biological indicator has the correct spore population and intrinsic resistance for the application.
- Confirm the Biological Indicator (BI) was stored under the manufacturer-recommended conditions.
- Check the viability of spores in the BI by incubating an unprocessed indicator (positive control) daily.
- Corroborate that the location of the BI in the chamber meets SOPs.
- Ensure that strict aseptic techniques were used during the culturing in case of spore strips.
- Ensure that the temperature at all locations within the incubator are the recommended by the manufacture.
- Make sure the incubator is calibrated.
- If a Self-Contained Biological Indicator (SCBI) was used, make sure the cap wasn't sealed until after it was exposed to the sterilization cycle.
- If the SCBI experiences "caramelization" or an amber color change (overexposure) verify that the sterilizer cycle parameters are within the corresponding range.
- In case of fluorescence SCBI, verify that the reading program is available, correctly selected and activated before breaking the SCBI ampoule.
- Verify that the chemical exposure indicator on the SCBI label correctly changed color after processing.
- In case of delayed incubation, check the BI holding time and conditions reported by the BI manufacturer.
- Do not activate the fluorescence SCBI until the reader is available for incubation.
- If SCBI, use the recommended crusher and shake the indicator down to ensure that the culture medium comes into contact with the inoculated spore.
- Do not remove the biological indicator from the incubator until the result is ready.
- Do not reincubate the fluorescence SCBI for a second rapid readout.
- Optionally, extended incubation can be performed as a fluorescence reading verification by evaluating the coloration of the culture medium after the recommended extended incubation time.
- If incubation for 7 days is required, perform the incubation in a humidified environment to avoid evaporation of the culture medium in the SCBI.
- Stop using of the sterilizer until satisfactory results are obtained from a repeated biological indicator test and all applicable quality assurance guidelines are met.