STERIS

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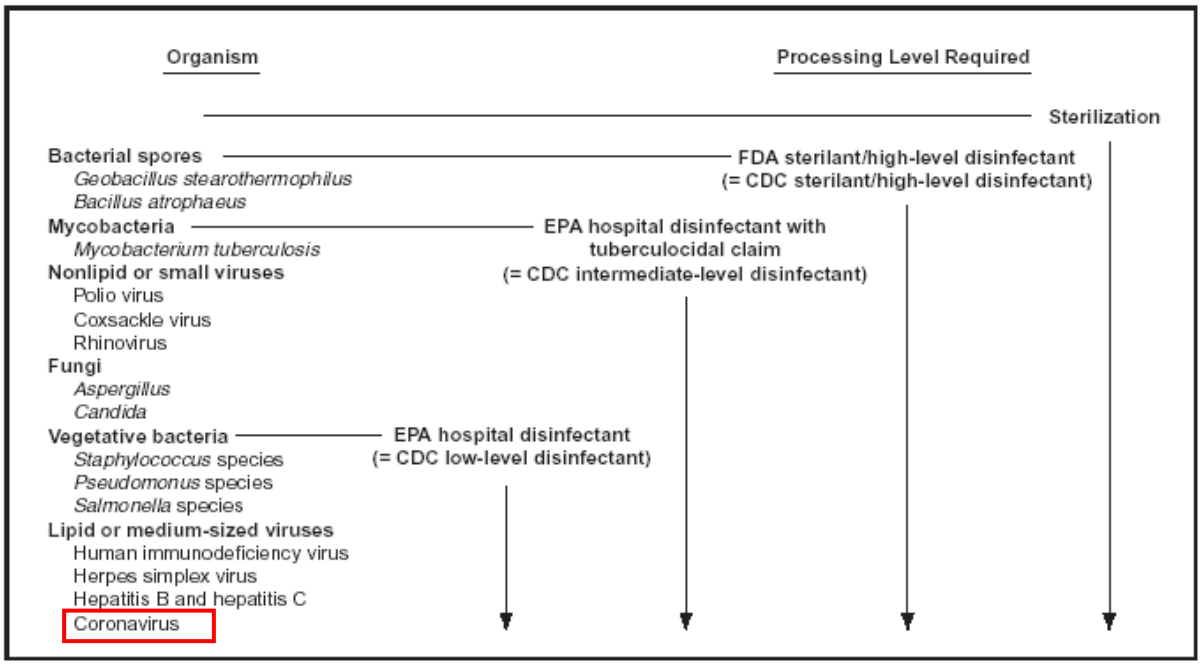
Dear Valued Customer:

These are challenging times in the healthcare environment today as you are on the front line of managing COVID-19. Keeping patients and employees safe and healthy and minimizing the risk of spreading the virus is at the forefront of daily life.

At STERIS, we have received many questions relating to the effectiveness of our infection prevention solutions to inactivate SARS-CoV-2 Coronavirus. The virus is classified as an enveloped virus and is relatively susceptible to inactivation on medical devices following the instructions for use for cleaning and disinfection/sterilization of the device or instrument, but infection prevention recommendations are similar to those already adopted for bloodborne pathogens such as HIV and Hepatitis B. STERIS has demonstrated effectiveness of its medical device reprocessing products (high-level disinfectants, liquid chemical sterilants, terminal sterilization processes) against many enveloped viruses and organisms that are more resistant to inactivation than coronavirus.

FIGURE. Decreasing order of resistance of microorganisms to germicidal chemicals



Source: Adapted from Bond WW, Ott BJ, Franke K, McCracken JE. Effective use of liquid chemical germicides on medical devices; instrument design problems. In: Block SS, ed. Disinfection, sterilization and preservation. 4th ed. Philadelphia, PA: Lea & Gebiger, 1991:1100.

Retrieved From: https://www.cdc.gov/mmwr/preview/mmwrhtml/figures/r217a2f.gif

Device and Equipment Reprocessing

Normal recommended infection prevention standard precautions for device reprocessing should be followed. These include consideration of the Spaulding Classification system and corresponding recommended reprocessing steps for non-critical, semi-critical and critical devices. Practices include safe transport of soiled articles and cleaning, disinfection and/or sterilization in accordance with the device manufacturer's instruction for use and the healthcare facility policies and practices.

Semi-critical devices should be cleaned and either sterilized or high-level disinfected as determined to be suitable for the device's intended use. Recommended STERIS products include the AMSCO®, Reliance® and Vision® brands of Washer-Disinfectors, Reliance® EPS Endoscope Reprocessing System, Revital-Ox RESERT® High Level Disinfectant, SYSTEM 1E®

and SYSTEM 1 endo Liquid Chemical Sterilant Processing Systems, the family of V-PRO® Low Temperature Sterilization Systems as well as the complete offering of steam sterilization products such as the family of AMSCO® Steam Sterilizers.

Critical devices should be cleaned and sterilized using a liquid chemical, gaseous or steam sterilization process according to the instructions for use provided by the device manufacturer as well as those of the sterilization system manufacturer. Recommended STERIS products include the SYSTEM 1E® Liquid Chemical Sterilant Processing System, V-PRO® Low Temperature Sterilization Systems as well as the complete offering of steam sterilization products such as the family of AMSCO® Evolution® Steam Sterilizers.

STERIS offers the Low Temperature Reprocessing Device Compatibility Matrix as a resource to confirm appropriate reprocessing methods for medical devices. This can be located on the STERIS website at https://ww1.steris.com/products/devicematrix/

STERIS is also receiving inquiries about the decontamination of Personal Protective Equipment (PPE), such as N95 masks, Safety Glasses, face shields, etc. For non-critical devices and equipment, use disinfectants that are both compatible with and labeled for use on medical devices. Consideration should also be given to the US CDC recommendation for disinfectants labeled for use on, and tested against, enveloped and non-enveloped viruses (typically intermediate or high-level disinfectants).

STERIS reprocessing solutions should be used in accordance within our FDA 510k cleared claims. In order to determine if the product can be effectively reprocessed, the product must be able to be cleaned and must fall within the cleared material claims and lumen (channel) lengths and diameter, if applicable. This detail can be accessed for V-Pro and RESERT from the links below.

Resert HLD: https://ww1.steris.com/media/pdf/resert/4455AW_Technical%20Data%20Monograph2015.pdf

V-Pro Max Low Temperature Sterilization System: https://ww1.steris.com/onbDocs/V431/1547/823762.pdf

We understand that additional questions may arise. If you have a question regarding the appropriate use of a STERIS reprocessing product, please contact STERIS at https://ww1.steris.com/products/devicematrix/dmContact.cfm?btnContact=Contact+Us.

In closing, please note that STERIS manufacturing facilities are fully operational, and we are continuing to fulfill orders for product to support the ongoing needs of your healthcare facility. In addition, the STERIS Service team is positioned to support you to ensure that your reprocessing equipment is up and running.

STERIS Corporation remains committed to your success in delivering patient care through this pandemic.
Thank you for all that you are doing to serve patients.

Best regards,

STERIS Corporation
Infection Prevention Technologies