The STERIS SYSTEM 1® Sterile Processing System is a method for sterilization for immersible surgical and diagnostic devices. The STERIS PROCESS™ uses a liquid chemical process for the rapid, low temperature destruction of microorganisms on the surfaces of surgical instruments and devices. Please consult the STERIS SYSTEM 1® Operators Manual for proper sterilization parameters.

KARL STORZ Products validated with the STERIS SYSTEM 1® Sterile Processing System

KARL STORZ Products not compatible with the STERIS SYSTEM 1® Sterile Processing System

KARL STORZ has conducted material compatibility and sterilization validation studies of KARL STORZ products using the STERIS SYSTEM 1® Sterile Processing System. The studies were conducted in conjunction with STERIS Corporation in accordance with AAMI[1] guidelines.

Material compatibility testing determines whether a device will withstand the STERIS PROCESS™ without significant impact on the materials or functionality of the device. Sterilization validation testing determines whether a device is actually sterile after exposure to a STERIS SYSTEM 1® sterilization cycle.

KARL STORZ devices were exposed to a minimum of 100 cycles of the STERIS SYSTEM 1® Sterile Processing System to determine material compatibility. Testing included various materials representative of the extensive KARL STORZ product line, including stainless steel and plastics.

Sterilization efficacy or validation testing was performed by KARL STORZ in conjunction with STERIS Corporation to show that the recommended STERIS SYSTEM 1® cycle parameters are capable of producing a minimum sterility assurance level (SAL) of 10^{-6}. All sterilization efficacy testing was done using the AAMI overkill method, which assumes that a sterilization cycle will be able to inactivate a resistant microbial challenge, such as a population of bacterial spores, to demonstrate the 10^{-6} sterility assurance level or SAL. Many of the devices used in the validation testing had lumens, Luer ports, hinges, and other moving parts that represent a challenge to a sterilization system. Please contact STERIS Corporation for the most current STERIS SYSTEM 1® processing options for KARL STORZ instruments.

Please note that any sterilization system must be properly maintained, calibrated, and used in accordance with the manufacturer's instructions to ensure the sterility of a device after processing. Please contact STERIS Corporation for complete information and proper maintenance procedures.

[1] Association for the Advancement of Medical Instrumentation. Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities; A Guide for Device Manufacturers. AAMI TIR No. 12-1994.

KARL STORZ Products compatible with and validated with the STERIS SYSTEM 1® Sterile Processing System

KARL STORZ and STERIS have validated the following types of instruments for sterilization efficacy and material compatibility:

- Many flexible endoscopes, including bronchoscopes, cytoscopes, ureteroscopes, intubation scopes, rhinopharyngolaryngoscopes, choledochoscopes, and hysteroscopes.[2]
- Rigid HOPKINS telescopes without instrument channels
- Semi-Rigid fiber optic telescopes[3]
- Video Cameras (except those that are designated as non-soakable).
- Fiberoptic and Fluid Light Cables
- Ureter Light probes
- Calcutript Connecting Cables
- Reusable HF cords
- Solid non-lumened instruments with no hinges or jaws

ONLY products listed above are compatible with the STERIS SYSTEM 1® Sterilization System. KARL STORZ does not recommend the use of the STERIS SYSTEM 1® for sterilization of any other products.

Please note that devices listed as compatible may exhibit cosmetic changes caused by the STERIS SYSTEM 1® Sterile Processing System that does not affect the functionality of the device.

Please note that devices with lumens must be processed with specific STERIS Quick Connect Kits and the associated STERIS tray. Please contact STERIS Customer Service for the most current processing options for KARL STORZ products.

Please note that all devices must be thoroughly cleaned prior to sterilization in the STERIS SYSTEM 1® Sterile Processing System.

The user must validate any deviations from the recommended STERIS SYSTEM 1® sterilization parameters. Please note that any sterilization system must be properly maintained, calibrated, and used in accordance with the manufacturer's instructions to ensure the sterility of a device after processing. Please contact STERIS Corporation for complete information and proper maintenance procedures.

[2] For the most current list of models that can be processed using the STERIS SYSTEM 1® Sterile Processing System contact STERIS Customer Service. Flexible endoscopes are compatible and validated only when processed following STERIS instructions with specific STERIS Quick Connect Kits and in the associated STERIS processing tray for flexible endoscopes.
[3] Semi-rigid fiber optic telescopes with instrument channels are compatible and have been validated only when processed following STERIS instructions and using specific Quick Connect Kits and the associated STERIS tray for KARL STORZ semi-rigid endoscopes.

KARL STORZ Products NOT compatible with the STERIS SYSTEM 1® Sterile Processing System

The sterility of the following devices cannot be assured using the STERIS SYSTEM 1® Sterile Processing System. However, these devices may be steam or ethylene oxide sterilized.

- Rigid Telescopes with instrument channels
- Working Elements
- Trocars/Sheaths
- Reusable tubing
- Insulated and non-insulated Click*line*™ Instruments
- Insulated and non-insulated surgical instruments (forceps, scissors, suction tubes, etc.)
- Hamou Magnifying Telescopes
- Motors and associated handpieces