Indications for use of STERRAD® Sterilization Systems

KARL STORZ Products that can be sterilized with STERRAD® Sterilization Systems

KARL STORZ Products which can not be sterilized with STERRAD® Sterilization Systems

KARL STORZ has conducted material compatibility and sterilization efficacy studies of KARL STORZ products with the STERRAD® Sterilization system.

These studies have been conducted in conjunction with Advanced Sterilization Products (ASP), in accordance with the AAMI[1] guidelines. Devices in these studies have been validated through at least one hundred consecutive STERRAD® cycles, with the exception of video cameras, which have been validated for two hundred consecutive cycles and telescopes which have been validated for three hundred cycles.

Twelve product categories were tested, representing the various materials, devices, and device configurations (i.e. lumens, hinges, etc.) of the extensive KARL STORZ product line. These devices were sterilized in accordance with the STERRAD® Sterilization System Operators Manual. Only STERRAD instrument trays and wraps recommended for use with the STERRAD® Sterilization System were used for the studies.

Material compatibility testing determines whether a device will withstand sterilization with STERRAD® without significant impact on the materials or functionality of the device. Sterilization efficacy testing determines whether a device is actually sterile after exposure to the STERRAD® sterilization cycle. Sterility testing was done using the AAMI overkill method to a sterility assurance level (SAL) of 10^{-6}. The results of these studies are presented below:

KARL STORZ Products, which can be sterilized with STERRAD Sterilization Systems:

- Rigid Telescopes (except HAMOU® I with eyepiece drive mechanism)
- Flexible Fiberscopes, Semi-rigid Fiberscopes and Microendoscopes[2]
- Video Cameras (except ENDOVISION XL)
- Fibre Light Cables
- Click*line*® Instruments, Insulated
- Click*line*® Instruments, Non-insulated
- Surgical Instruments, Insulated (forceps, scissors, etc.)
- Surgical Instruments, Non-insulated (forceps, scissors, etc.)
- Trocars / Shafts / Cannulas / Obturators
- Working Elements
- Ureter Light Probe
- High frequency Cords

EHL Probe Cable (part no. 27080 KA)

Devices in the "compatible list" may exhibit cosmetic changes caused by STERRAD sterilization that do not affect the functionality of the device.

Please note that there are restrictions as to what may be sterilized in the STERRAD Sterilization Systems based on lumen size and materials. Please follow the instructions in the STERRAD User's manual or contact ASP directly to ensure the sterility of the device.

KARL STORZ Products, which can not be sterilized with STERRAD® Sterilization System:

- HAMOU® I telescopes with eyepiece drive mechanism (26156 B/BU, 26157 BU, 27156 BU, 28720 BH, 7200 BH BH)
- Video Camera ENDOVISION® XL reusable tubing sets, e.g. for ENDOFLATOR®, ENDOMAT®, HYDROMAT, Resectoscope

Please note that special materials and containers for packaging and storage are necessary to ensure sterility. Validations have been performed using the packaging recommended by Johnson & Johnson. KARL STORZ 39501 series baskets are also suitable for use.

Please keep in mind that any deviations from the recommended STERRAD sterilization parameters must be validated by the user. KARL STORZ recommends contacting Johnson & Johnson (or ASP) when there are any questions regarding the safety of sterilization with the STERRAD System.

If you have any other questions concerning cleaning, sterilization or care of our products, please contact our Quality Assurance department.

[1]Association for the Advancement of Medical Instrumentation. Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers: AAMI RDA – TIR12 - 8/94. Arlington (VA): AAMI, 1994, AAMI Technical Information Report
[2]The fiberscopes were validated in co-operation with Johnson & Johnson and may only be valid outside of the USA.
[3]The recommendations given on this webpage may not be valid in the US contact KSEA or ASP for additional information.