

March 11, 2011

Re: Medivators AERs High Level Disinfection of the KARL STORZ Flexible GI Videoscopes

Dear Valued Customer:

KARL STORZ Endoscopy-America, Inc. shares the responsibility with our customers of providing the best reprocessing practices. KARL STORZ, in collaboration with Minntech Corp., has completed the high level disinfection validations to represent reprocessing of the KARL STORZ Flexible GI Videoscopes. The high level disinfection validations met the required 6-log reduction of the biological indicators, *Mycobacterium terrae* ATCC # 15755, using the representative Medivators AER systems.

The Medivators AER table matrix (attached) lists the qualified KARL STORZ GI Videoscopes, Medivators Automated Endoscope Reprocessors (AER) and specific Medivators hook-up connectors.

Note: The Dual Sided Disinfector (DSD), Single Sided Disinfector (SSD), and DSD Edge Hook-up Connectors require the KARL STORZ Washer/Disinfector Connector Set 13991CK.

Should you have any further questions regarding this subject or require additional assistance, please don't hesitate to KARL STORZ Technical Support at (800) 421-0837. You may also contact Minntech Corp. Technical Support at (800) 444-4729. Minntech Corp. is the manufacturer of Medivators AERs.

Sincerely,



Tony Rosales
Sterilization Manager
Regulatory Affairs Department

Ref.: 2011-012-AR

**Medivators Automated Endoscope Reprocessors
KARL STORZ Flexible GI Videoscopes**

| KARL STORZ Flexible GI Videoscopes | | Medivators AERs and Hook-up Connectors | | | | | | | | | | | | | | | | | |
|--|-----------------|--|---|--|-------------|------------|-------------------|--|---|--|--|------------|--|--|---|--|--|------------|--|
| Description | Model No. | CER-1 (MV-1) | CER-2 (MV-2) | DSD / SSD | DSD Edge | Advantage | Advantage Plus | | | | | | | | | | | | |
| <i>Single Channel</i> | | | | | | | | | | | | | | | | | | | |
| Gastrosopes | 13800 -NKS/-PKS | CLM-110-HU0080 (x4) and KARL STORZ Connector Set 13991CK | CLM-110-HU0080 (x3), CLM-110-HU0136, and KARL STORZ Connector Set 13991CK | DSD-110 -HU0163 and KARL STORZ Connector Set 13991CK | | 2-8-540HAN | | | | | | | | | | | | | |
| | 13801 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13802 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13803 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13804 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13805 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13808 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13820 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| 13821 -NKS/-PKS | | | | | | | | | | | | | | | | | | | |
| Duodenoscope | 13880 -NKS/-PKS | | | | | | | CLM-110-HU0080 (x1), CLM-110-HU0136 (x2), and KS Connector Set 13991CK | CLM-110-HU0080 (x3), CLM-110-HU0136 (x1), CLM-110-HU0132 (x1), and KS Connector Set 13991CK | DSD-110-HU0163, DSD-110-HU0113, and KS Connector Set 13991CK | | 2-8-640HAN | | | | | | | |
| | 13881 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13882 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13885 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| Sigmoidoscopes | 13900 -NKS/-PKS | | | | | | | | | | | | | CLM-110-HU0080 (x1), CLM-110-HU0136 (x2), and KS Connector Set 13991CK | CLM-110-HU0080 (x3), CLM-110-HU0136 (x1), CLM-110-HU0132 (x1), and KS Connector Set 13991CK | DSD-110-HU0166 and KS Connector Set 13991CK | | 2-8-740HAN | |
| | 13901 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| Colonoscopes | 13902 -NKS/-PKS | CLM-110-HU0080 (x1), CLM-110-HU0136 (x2), and KS Connector Set 13991CK | CLM-110-HU0080 (x3), CLM-110-HU0136 (x1), CLM-110-HU0132 (x1), and KS Connector Set 13991CK | DSD-110-HU0166 and KS Connector Set 13991CK | | 2-8-740HAN | | | | | | | | | | | | | |
| | 13903 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13904 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13905 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13906 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13907 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| 13924 -NKS/-PKS | | | | | | | | | | | | | | | | | | | |
| <i>Single Channel w/ Jet Ventilation Channel</i> | | | | | | | | | | | | | | | | | | | |
| Gastrosopes | 13807 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| Colonoscopes | 13925 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| <i>Dual Channels w/ Jet Ventilation Channel</i> | | | | | | | | | | | | | | | | | | | |
| Gastrosopes | 13806 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| Colonoscopes | 13910 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| | 13911 -NKS/-PKS | | | | | | | | | | | | | | | | | | |
| KARL STORZ Recommended HLD Agents for Medivators AERs: | | CIDEX, CIDEX OPA, or Rapicide | | | Rapicide PA | Rapicide | Rapicide PA | | | | | | | | | | | | |

NOTE: The Countertop Endoscope Reprocessor (CER), Dual Sided Disinfector (DSD), Single Sided Disinfector (SSD), and DSD Edge Hook-up Connectors require the KARL STORZ Washer/Disinfector Connector Set 13991CK.