URGENT FIELD SAFETY NOTICE

ATTENTION	**Central Sterilisation Department**
TYPE OF ACTION	Voluntary FIELD SAFETY NOTICE
REF / DATE	ASP14/2013 (CL-90098-011/November 14, 2013)
PRODUCT	The purpose of this communication is to inform you that you should discontinue processing the following Karl Storz fiberscopes in STERRAD® Systems. Bronchoscope models: 11001BN1, 11002BD1, 11004BC1, 11009BC1 Intubation Fiberscope models:11301BN1, 11302BD1, 11302BD2, 11304BC1, 11340BC1, 11301BND1, 11302BDD1, 11302BDD2
REASON	ASP has determined that these endoscope models incorporate a lumen material not included in the cleared claims for STERRAD® processing. These endoscopes may contain a polyurethane material in the suction channel location and that this material is not listed in the current claims for interior channels (lumens) for processing in STERRAD® Systems.
ACTION	Please complete the following steps below: • Provide this notice to anyone in your facility that needs to be informed. • Post this notice where appropriate. • Maintain awareness of this notice.
CONTACT	You are receiving this letter because our records indicate that you may own a STERRAD® System and may also own one of the Karl Storz fiberscopes listed. If you have additional questions about this action, please contact your Sales Representative or call [Affiliate Name]. ASP is currently collaborating with KARL STORZ Endoskope to determine the sterilization impact of the suction port lumen material. Please contact your local KARL STORZ Endoskope Technical Support for alternative reprocessing instructions. We apologize for any inconvenience this will cause you, but rest assured it is our utmost intent to make this process as easy for you as possible.
CONFIRMATION	This action has been notified to the appropriate Regulatory Agencies.