



T H E G U L F F I B E R O P T I C S G R O U P

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May 5, 2010

Dear Valued Customer:

This letter is to inform you that the Gulf Medical Fiberoptics, Inc. has validated the following light cords in the STERRAD® 100S, 200, NX and 100NX Systems:

- Rigid Endoscopy Fiberoptic Light Cord 475010180FRGY
- Rigid Endoscopy Fiberoptic Light Cord 184071806BL
- Rigid Endoscopy Fiberoptic Light Cord 395010180FRGY
- Rigid Endoscopy Fiberoptic Light Cord 2105010180FRGY
- Rigid Endoscopy Fiberoptic Light Cord 1750101800CL

Testing was performed in accordance with AAMI TIR No.12-2004 guidelines, "Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers."

Please refer to the STERRAD System User's Guides for general reprocessing instructions, including proper cleaning, and drying, and packaging information prior to reprocessing any medical device in a STERRAD System. Specific sterilization questions should be made directly to Advanced Sterilization Products by calling 1-888-STERRAD.

All medical devices should be inspected prior to use to ensure patient safety. Do not use any device if there is a defect or damage noted during the inspection.

It is important to note that Gulf Medical Fiberoptics, Inc. cannot guarantee that any medical device repaired by a third-party company will be compatible in a STERRAD Sterilization System. Please check with the facility for compatibility information prior to reprocessing.

For questions related to the medical device, please contact your local Gulf Medical Fiberoptics representative.

Sincerely,

Craig S. Vogeley  
Vice President, Operations  
Gulf Medical Fiberoptics, Inc.

### Gulf Medical Fiberoptics, Inc.

To ensure patient safety, Advantec SpineLight Products, a Division of Ethicon, Inc. (ASP), is requesting that all Medical Device Manufacturers (MDM) review the list of medical devices manufactured and/or distributed by the MDM that are identified in the STERRAD Sterility Guide (SSG) for accuracy.

Please refer to the attached information sheet regarding STERRAD System's materials and laser claims that will assist to complete this assessment form. Your signature will indicate that you wish your devices to be added to this STERRAD Sterility Guide for the appropriate STERRAD System, and to acknowledge that substantial changes to your device will require reassessment.

Thank you, in advance, for your full cooperation.

Part A: Initial Assessment - Devices to be Added to the STERRAD Sterility Guide (SSG)									
STERRAD System (10CS, 200, 50, 100NX, 100NX)	Device Name	Device Model	Does the Device Meet Material and Laser Claims? (Y or N)	Claims US only (US), Outside US Only (OUS), or Worldwide (WW)	Current Version of MDM Document - Rev. and Date, if available (i.e. IFU, Bulletin)	Manufacturer's Notation	ASP Use Only Quality R&D		
ALL	Rigid Endoscopy Fiberoptic Light Cord	475010180FRGY	Y	WW	Customer Letter (5/5/2010)	N/A			
ALL	Rigid Endoscopy Fiberoptic Light Cord	184071306BL	Y	WW	Customer Letter (5/5/2010)	N/A			
ALL	Rigid Endoscopy Fiberoptic Light Cord	396010180FRGY	Y	WW	Customer Letter (5/5/2010)	N/A			
ALL	Rigid Endoscopy Fiberoptic Light Cord	2108C12180FRGY	Y	WW	Customer Letter (5/5/2010)	N/A			
ALL	Rigid Endoscopy Fiberoptic Light Cord	17501018000CL	Y	WW	Customer Letter (5/5/2010)	N/A			
Part B: Annual Re-Assessment - Devices Currently in the STERRAD Sterility Guide (SSG)									
STERRAD System (10CS, 200, 50, 100NX)	Device Name	Device Model	Does the Device Continue to Meet Material and Laser Claims? (Y or N)	Claims US only (US), Outside US Only (OUS), or Worldwide (WW)	MDM Document - Rev and Date, if available (Please indicate if there has been a new revision in the past year, and provide a copy of the page with this form)	REMAIN on SSG? (Y or N)	ASP Use Only Quality R&D		
n/a	n/a	n/a	n/a	n/a	n/a	n/a			
n/a	n/a	n/a	n/a	n/a	n/a	n/a			

MDM Representative Name and Title: Chris S. Vossler, V.P. Operations Signature and Date: \_\_\_\_\_  
 ASP USE ONLY: Quality Review Name, Signature and Date: \_\_\_\_\_ R&D Review Name, Signature and Date: \_\_\_\_\_  
 CO-1000043 Please email completed form to mdmprogram@its.jnj.com or fax to (949) 450-3855 Attn: MDM Program T-1C1352 Rev. D