ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

URGENT: DEVICE RECALL

Attention: Operating Room Director and Materials Management

April 21st, 2006 REF: ProbePlusII-2006-04-21

PRODUCT	Specific production batches as identified by Ethicon-Endo Surgery, Inc. Lot numbers. **ENDOPATH® Probe Plus II Electrosurgical Suction Irrigation product codes:** **ENDOPATH® PROBE PLUS II Handles** EPH01 ENDOPATH® PROBE PLUS II, Foot-Controlled PistolGrip Handle EPH02 ENDOPATH® PROBE PLUS II, Hand-Controlled PistolGrip Handle EPH04 ENDOPATH® PROBE PLUS II, Hand-Controlled PencilGrip Handle **ENDOPATH® PROBE PLUS II Electrodes** EPS01 ENDOPATH® PROBE PLUS II, Hook Electrode, 5mm shaft, 34cm length, hollow tip electrode EPS02 ENDOPATH® PROBE PLUS II, Spatula Electrode, 5mm shaft, 34cm length, hollow tip electrode EPS03 ENDOPATH® PROBE PLUS II, Right Angle Electrode, 5mm shaft, 34cm length, hollow tip electrode EPS04 ENDOPATH® PROBE PLUS II, Curved Dissector Electrode, 5mm shaft, 34cm length, hollow tip electrode EPS06 ENDOPATH® PROBE PLUS II, Spatula Electrode, 5mm shaft, 29cm length, hollow tip electrode EPS08 ENDOPATH® PROBE PLUS II, Curved Dissector Electrode, 5mm shaft, 29cm length, hollow tip electrode EPS09 ENDOPATH® PROBE PLUS II, Needle Electrode, 5mm shaft, 29cm length, hollow tip electrode **ENDOPATH® PROBE PLUS II Irrigation** EPS11 ENDOPATH® PROBE PLUS II, Open End Suction/Irrigation Cannula, 10mm shaft, 34cm length **ENDOPATH® PROBE PLUS II Cannulas** EPS13 ENDOPATH® PROBE PLUS II, Flexible Fiber Cannula, 5mm shaft, 29cm length ***See Attachment 1 for identification of product and list of affected product codes and manufacturing Lot numbers.*** ***See Attachment 2 for Image Identification of Product Code and Lot Number.***
REASON	Ethicon Endo-Surgery Inc. is conducting a voluntary product recall of specific production lots of the **ENDOPATH® Probe Plus II Electrosurgical Suction Irrigation Products**. We have initiated this recall for specific production lots of ENDOPATH® Probe Plus II because the possibility exists that a seal void in the ENDOPATH® Probe Plus II packaging may have compromised the sterility of the device. **The voluntary recall is being conducted with the full knowledge of the Food and Drug Administration (FDA) and EU Health Authorities.** **DO NOT USE THE ABOVE MENTIONED PROBE PLUS PRODUCT CODES WITH THE AFFECTED LOT NUMBERS!** We need your help in ensuring that **all affected product** as identified by the Lot Number of the ENDOPATH® Probe Plus II Electrosurgical Suction Irrigation Products are located, accounted for, and returned to [Affiliate Name].

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ACTION	1) Examine your inventory immediately to determine if you have affected product on hand. (See Attachment 1) **Remove** the affected product. 2) Fill out the Business Reply Form / Packing Slip Form and fax it back to [Affiliate Name], **even if you do not have affected product**. Please reference **ProbePlusII-2006-04-21** . If you have product to be returned, keep a copy of this form for your records, enclose a copy with the product, and use the pre-paid shipping label to return to: [Affiliate Name / Affiliate Address] 3) **Ask your sales representative to assist you in the completion of this voluntary recall process should you need assistance.**
OTHER INFORM-ATION	[Affiliate Name] will process your individual product return with a no charge exchange of equivalent product, subject to availability. Please share this information with all of the appropriate staff at your facility. 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. If you have additional questions about this action, please feel free to contact your Sales Representative or call [Affiliate Name].