Johnson & Johnson MEDICAL

January 28, 2009

Encik Zamanee Bin Abdul Rahman
Medical Device Bureau
Ministry of Health Malaysia
Level 5, Block E6 Complex E
Federal Government Adminstrative Centre
62590 Putrajaya, Malaysia

Re: Voluntary Product Correction: STERRAD® 50 Sterilizer

Dear Sir,

Description of Event:
Advanced Sterilization Products division of Ethicon, Inc. (ASP) is notifying customers of STERRAD® 50 Sterilizers about a remote circumstance that could cause a capacitor in the vacuum pump component within STERRAD® 50 System to overheat and potentially create a hazardous condition inside of the system, resulting in smoke and/or fire. Based on our risk assessment, there is a low possibility of this malfunction occurring, as ASP is aware of only two such incidents since the system was released in 1997.

This condition only impacts STERRAD 50 Systems manufactured prior to 2004.

This letter is to inform you of the situation and what ASP will do to correct them.

There were no adverse events or malfunctions reported in our countries.

ASP is mailing customer notifications as attached in a Product Correction envelope starting the week of February 2, 2009.

Product Correction Strategy:
Customer notifications will be sent to all customers with STERRAD® 50 Sterilizers. Every effort will be made to update all affected products in a timely manner. This voluntary notification is being conducted with the full knowledge of the US Food & Drug administration (FDA). Other global regulatory authorities will also be advised of this issue as required by local regulations.

Please find attached the product correction notification letter.

Respectfully,

Ong Yean Ting
Regulatory Affairs Manager

Enclosure:
Customer Letter

Johnson & Johnson MEDICAL
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