



January 12, 2009

URGENT: PRODUCT CORRECTION
Specific STERRAD® 50 Sterilizers

Dear Risk Manager:

Advanced Sterilization Products (ASP) is notifying you of a remote circumstance that could cause a capacitor in the vacuum pump component within your 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 the U.S. in 1999.

This condition only impacts STERRAD 50 Systems with serial numbers listed on page two of this notification. You are being informed of this situation because our records indicate that your facility has one of the affected STERRAD 50 Systems.

Please distribute this notification to all STERRAD 50 System users in your facility.

Actions Required if Malfunction Occurs

If you see smoke or smell a burning odor in or around your STERRAD 50 System, ASP strongly recommends that you follow your facility's safety protocols and if possible, immediately disconnect the STERRAD 50 System from its electrical source. Please contact ASP to schedule an onsite visit to investigate the issue. If the issue is caused by a malfunctioning capacitor in the vacuum pump, we will replace the malfunctioning component right away.

Actions We Are Taking

To correct this situation, an ASP Field Service Engineer (FSE) will be visiting your facility within the next sixty days to replace the capacitor in the vacuum pump on your affected STERRAD 50 System with a capacitor of a different design. Your Field Service Engineer (FSE) will contact you as soon as possible to schedule this visit.

We regret any inconvenience this product correction may cause you or your staff. If you have any questions or need assistance, please call the ASP Customer Care Center at 888-783-7723, option 2.

Thank you for your valued partnership and continued support of STERRAD Sterilization Systems.

Sincerely,

A handwritten signature in blue ink that reads "Mark Johnson".

Mark Johnson
Vice President, Quality Assurance, Regulatory Affairs and Process Excellence

3 Technology Drive, Irvine, CA 92618. Tel: 949.581.5799. Fax: 949.581.5997

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.

a **Johnson & Johnson** company

STERRAD® 50 Sterilizer Serial Numbers

10050000502	10050000710	10050000867	10050021097	10050035059	10050035148
10050000505	10050000712	10050000868	10050021099	10050035060	10050035149
10050000509	10050000713	10050000869	10050021100	10050035061	10050035153
10050000510	10050000714	10050000872	10050021103	10050035063	10050035154
10050000513	10050000717	10050000873	10050021104	10050035065	10050035155
10050000516	10050000725	10050000874	10050021106	10050035066	10050035156
10050000517	10050000727	10050000877	10050021110	10050035067	10050035157
10050000532	10050000728	10050000895	10050021111	10050035070	10050035158
10050000534	10050000729	10050000897	10050021112	10050035071	10050035160
10050000545	10050000730	10050010911	10050021116	10050035074	10050035162
10050000548	10050000739	10050010916	10050021136	10050035075	10050035164
10050000549	10050000745	10050010918	10050021137	10050035076	10050035166
10050000551	10050000756	10050010922	10050021139	10050035077	10050035167
10050000552	10050000759	10050010941	10050021140	10050035078	10050035170
10050000554	10050000760	10050010945	10050021142	10050035086	10050035171
10050000564	10050000762	10050010948	10050021145	10050035094	10050035172
10050000567	10050000767	10050010952	10050021146	10050035100	10050035173
10050000570	10050000768	10050021012	10050021147	10050035101	10050035174
10050000574	10050000773	10050021013	10050021148	10050035103	10050035175
10050000576	10050000774	10050021016	10050021149	10050035104	10050035179
10050000588	10050000779	10050021022	10050021150	10050035105	10050035181
10050000597	10050000782	10050021029	10050035004	10050035106	10050035182
10050000606	10050000784	10050021030	10050035006	10050035111	10050035184
10050000609	10050000800	10050021031	10050035008	10050035116	10050035185
10050000613	10050000801	10050021032	10050035011	10050035117	10050035188
10050000614	10050000803	10050021033	10050035013	10050035118	10050035196
10050000615	10050000804	10050021034	10050035014	10050035119	10050035204
10050000616	10050000806	10050021036	10050035015	10050035121	10050035205
10050000617	10050000813	10050021037	10050035022	10050035124	10050035321
10050000618	10050000815	10050021038	10050035023	10050035126	10050035323
10050000621	10050000822	10050021041	10050035027	10050035127	10050035324
10050000624	10050000832	10050021042	10050035028	10050035128	10050035385
10050000625	10050000834	10050021043	10050035030	10050035129	10050970298
10050000627	10050000835	10050021045	10050035034	10050035130	10050970344
10050000635	10050000837	10050021046	10050035035	10050035131	10050980382
10050000644	10050000840	10050021049	10050035036	10050035132	10050980383
10050000648	10050000844	10050021050	10050035037	10050035134	10050980478
10050000653	10050000849	10050021054	10050035039	10050035135	10050980356
10050000662	10050000850	10050021059	10050035041	10050035136	10050980408
10050000673	10050000852	10050021060	10050035042	10050035137	10050980434
10050000676	10050000855	10050021064	10050035044	10050035139	10050980450
10050000680	10050000857	10050021069	10050035046	10050035140	10050980452
10050000686	10050000858	10050021087	10050035050	10050035141	10050980464
10050000692	10050000863	10050021092	10050035051	10050035142	10050970312
10050000694	10050000864	10050021094	10050035054	10050035143	10050000500
10050000705	10050000866	10050021095	10050035055	10050035144	