Duke Health
Raleigh Hospital

June 20, 2005

Dear

Since you were a patient at Duke Health Raleigh Hospital late last year, you may have concerns about recent media reports regarding surgical instruments accidentally exposed to hydraulic fluid prior to sterilization.

In January, you were notified of this problem with the cleaning process of surgical instruments which took place in November and December. At that time, our experts had found no evidence that the sterilization process was affected despite the fact the fluid was accidentally substituted for detergent in one step of a multistage, intensive high-heat cleaning process. Neither had they found a notable increase in infection rates at Duke Health Raleigh Hospital for patients treated during this period.

We now have some important new information to share with you, which supports those original conclusions and should be reassuring to you. We have just received a final report from Professor William A. Rutala, Ph.D., M.P.H., director of the Statewide Program in Infection Control and Epidemiology at the UNC School of Medicine. Dr. Rutala and his team of scientists investigated whether hydraulic fluid applied to surgical instruments made the sterilization process less effective. Dr. Rutala and his team recreated the situation and concluded the sterilization of the instruments was fully effective. Because these findings are so important, we wanted to share Dr. Rutala's exact words with you.

> "In these laboratory experiments, we found that replacing cleaning detergent with hydraulic fluid did not alter the effectiveness of the sterilization process as high numbers of clinically-relevant bacteria and standard test spores (relatively resistant to the sterilization process) were completely inactivated. Our previous research has demonstrated that surgical instruments are most commonly contaminated with less than 100 vegetative bacteria (Am J Infect Control 1998;26:143). Thus, our recent experiments, which used much higher numbers of vegetative bacteria, provide assurance that infection would not result from instruments coated with hydraulic fluid and then sterilized. The use of high numbers of spores, which are relatively resistant to sterilization, further supports our conclusion that sterilization was not adversely affected by hydraulic fluid."

In an effort to be even more confident of the safety and welfare of our patients, Duke also has obtained the expertise of other outside scientists to conduct a trace chemical analysis

of the surgical instruments that had been processed with the fluid. Given the unusual nature of this situation, these scientific experts had to create a brand-new method of analysis that took more time than we had hoped.

Their preliminary results, when combined with our monitoring of infection rates and Dr. Rutala's external report, reassured us that our patients have not been put at risk. As soon as we have the final report on the chemical analysis, which we expect in the next few weeks, we will share the results with you and your physicians.

We recognize that despite these findings by scientific experts, you may continue to be concerned that this incident may have affected your health. To help address such concerns, we have arranged for two physician experts in occupational and environmental medicine, Dr. Dennis Darcey and Dr. Carol Epling, to consult at your request with you and your physician on this matter. To make an appointment with either Dr. Darcey or Dr. Epling or to learn more about this service, please call 919-286-3232, ext. 223. Ms. Ellen O'Briant at the Duke Occupational Health Research Triangle Clinic will assist you. The clinic is in Research Triangle Park at 1005 Slater Road, Suite 101, Durham NC 27705.

You placed trust in Duke Health Raleigh Hospital when you chose to come to us for your medical care. We want you to know that we value that trust. We regret when any patient suffers. Unfortunately, we also know from long experience that there is always some risk of an undesirable outcome in any procedure, even under the best of circumstances. We can assure you that the physicians, nurses and staff at Duke Health Raleigh Hospital sincerely regret any concerns you may have experienced following your care and look forward to the opportunity to meet any healthcare needs you may have in the future.

If you have additional questions or concerns about the information in this letter, please contact Cindy Nordlund at 919-954-3123.

Sincerely,

James P. Knight
CEO
Duke Health Raleigh Hospital

Victor J. Dzau
President, CEO
Duke University Health System