



January 6, 2012

RE: Reprocessing Olympus Flexible Endoscopes Exposed to CJD

Dear Healthcare Professional,

This letter is in response to your recent inquiry regarding the reprocessing of Olympus flexible endoscopes (medical and surgical) exposed to the proteinaceous infectious agent, or prion, that causes Creutzfeldt - Jakob disease (CJD). The CJD agent presents a unique infection control challenge because it exhibits an unusual resistance to conventional disinfection and sterilization methods. In an effort to provide our customers with information, Olympus has reviewed various recommendations for the reprocessing of medical devices exposed to the CJD agent. However, Olympus has not tested the efficacy of these proposed methods, and therefore cannot recommend these methods for reprocessing Olympus flexible endoscopes contaminated with the CJD agent. The following information is provided for your reference only and should not be considered a recommendation or endorsement for the reprocessing of Olympus flexible endoscopes contaminated with the CJD agent.

At this time, there have been 6 reported cases of iatrogenic transmission of the CJD agent associated with contaminated medical equipment, all of which occurred prior to 1976 before the implementation of standard sterilization procedures. Of the six cases linked to the use of contaminated equipment, four were associated with neurosurgical instruments, and two with stereotactic EEG depth electrodes. In addition, there are no known cases of iatrogenic transmission of the CJD agent from endoscopy.

A number of organizations have proposed guidelines for the reprocessing of medical instruments exposed to the CJD agent. The World Health Organization (WHO) has developed infection control guidelines for preventing iatrogenic transmission of the CJD agent. Proposed recommendations for the reprocessing of heat-sensitive medical instruments, such as endoscopes, exposed to the CJD agent include immersion in sodium hypochlorite (NaClO) or sodium hydroxide (NaOH) for one hour. NaOH is extremely corrosive to flexible endoscopes and is not recommended for use. However, Olympus has performed material compatibility testing and concluded that Olympus flexible endoscopes can withstand up to 25, one-hour immersions in sodium hypochlorite (NaClO, 2% available chlorine concentration). Excessive immersion beyond this may cause corrosion and water leaks.



It is important to note that Olympus has not tested the efficacy of immersion in NaClO and makes no claims regarding the effectiveness of this procedure for reprocessing endoscopes contaminated with the CJD agent. Olympus only confirms the material compatibility of NaClO with Olympus flexible endoscopes.

To evaluate reprocessing any medical instrument exposed to the CJD agent, published guidance documents recommend that a comprehensive risk assessment be performed. The risk assessment is based upon three primary criteria: the CJD status of the patient (high or low risk), the potential infectivity of the tissue examined (high, low or no infectivity), and the classification of the medical device (critical vs. semi-critical). Olympus recommends that you consult with your infection control department and/or industry experts to determine a strategy that reduces or eliminates the risk of iatrogenic transmission of the CJD agent.

Olympus continues to monitor published studies and guidance regarding the destruction or inactivation of the agents responsible for transmissible spongiform encephalopathies, including variant CJD (vCJD), and will review its recommendations as additional information becomes available. Below is a list of useful references that provide guidance on reprocessing medical instruments exposed to the CJD agent.

If you have any additional questions, please contact your local Olympus sales representative or the Olympus Technical Assistance Center at 1-800-848-9024 (United States). Thank you.

Sincerely,

A handwritten signature in black ink, reading "Mary Ann Drosnock". The signature is written in a cursive, flowing style.

Mary Ann Drosnock, MS, CIC
Scientist, Clinical Affairs
maryann.drosnock@olympus.com



References

Alvarado, CJ. APIC guideline for infection prevention and control in flexible endoscopy. *Am J Infect Control* 2000; 28: 138-155.

Centers for Disease Control and Prevention. Questions and Answers: Creutzfeldt-Jakob disease infection control practices, available at http://www.cdc.gov/ncidod/dvrd/cjd/qa_cjd_infection_control.htm [accessed 6 January 2012]

Rutala, WA, and Weber DJ. Creutzfeldt-Jakob disease: recommendations for disinfection and sterilization. *Clinical Infectious Diseases* 2001; 32: 1348-1356.

Rutala, WA, and Weber DJ. Managing the risk of nosocomial transmission of prion diseases. *Current Opinion in Infectious Diseases* 2002 Aug.15 (4): 421-5.

United Kingdom, Department of Health, Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee. Transmissible spongiform encephalopathy agents: safe working and the prevention of infection, Annex F: decontamination of endoscopes: available at http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/annexf_amended-30mar07.pdf [accessed 6 January 2012].

World Health Organization. WHO infection control guidelines for transmissible spongiform encephalopathies; available at http://whqlibdoc.who.int/hq/2000/WHO_CDS_CSRAPH_2000.3.pdf [accessed 6 January 2012].