



**Joint AAE/CAE Special Committee on Single Use Endodontic Instruments**  
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**Final Report**  
**January 11, 2011**  
**Single Use Instruments**

**Preamble**

Endodontic instruments, particularly files and reamers have been designated as single use instruments (SUI) in some dental jurisdictions. This action has arisen out of concern for the difficulties encountered in their cleaning and sterilization after use and the possibility that they may act as vehicle for disease transmission when re-used. Of particular concern is the transmission of prion protein, a pathogenic isoform of a common host cell receptor, which causes acquired iatrogenic Creutzfeldt-Jakob Disease (iCJD), a type of the spongiform encephalopathy. No treatment or prophylaxis is available for this disease and its acquisition nearly always proves fatal.

At present there also is no universal standard for the preparation and sterilization of endodontic instruments prior to re-use. Most current methods fall short of consistently rendering instruments surgically sterile. Disease transmission associated with the re-use of endodontic hand and rotary files and reamers; however, has not proven itself to be a clinical problem in endodontic practice. Nonetheless, the threat of prion transmission via this route has become the basis for the decision to mandate that all such instruments be designated single use instruments (SUI) in some countries. As a result of the measures taken in those jurisdictions the Special Committee on Single Use Instruments was formed to evaluate and summarize the strength of the current scientific evidence supporting the standard concerning single use instruments that was adopted by the Alberta Dental Association & College. In addition the Committee was charged to evaluate any other relevant scientific evidence, consider what approaches should be taken to address this issue and to provide recommendations, whether the single-use designation for all instruments used within the root canal is warranted at this time.

## **Risk of Transmission of iCJD Via Endodontic Treatment**

While the prion protein has reportedly been transmitted to medical patients through exposure to blood, inadequately sterilized neurosurgical instruments and a variety of cadaver-derived materials, there has never been a confirmed case of iCJD transmitted through dental treatment. Much of the concern regarding its transmission through dental treatment has arisen from the identification of prion protein in dental and oral tissue of animals that have been experimentally infected with prions. Human studies have failed to show the presence of prions in similar tissues of patients with variant CJD (vCJD), a form of disease acquired through the consumption of infected animal tissue. The National Institute of Neurological Disorders and Stroke and the World Health Organization (WHO) have estimated the worldwide incidence of CJD caused by all manner of transmission to be 1 per 1,000,000 people. In 2006, the total number of iCJD cases reported worldwide was 405. In 2009 the US recorded only 3 cases of vCJD, 2 of which were likely to have been acquired abroad. There was no record of a case of iCJD reported in the USA at that time. When combined with a WHO classification of “low risk” potential for prion transmission through exposure to pulp tissue, it is highly unlikely a patient would acquire prion disease during an endodontic procedure. If endodontic hand and rotary files and reamers were to be mandated to be single use in any dental jurisdictions, it would certainly impact the cost of endodontic services and could possibly make these services less affordable to many patients. The American Association of Endodontists (AAE) and the Canadian Academy of Endodontics (CAE) have always stressed the importance of maintaining the natural dentition and have striven to maximize patients’ access to care. It is for this reason that the Special Committee on Single Use Endodontic Instruments does not deem it necessary to recommend that all endodontic hand and rotary files and reamers be designated as single use items at this time. The Special Committee does recommend that clinicians continue to adopt a vigilant and cautious approach in monitoring patient health, use acceptable methods to clean and sterilize endodontic instruments, and exercise sound clinical judgement in the selection of instruments for re-use. Hand and rotary files and reamers selected for re-use would include those that do not demonstrate surface or flute defects, those that have not lost their cutting efficiency, and those that have not been used on patients diagnosed with CJD. It is recommended that when a patient with confirmed CJD receives endodontic treatment, all instruments used in the root canal be discarded. The Committee also recommends that the AAE establish a database of relevant literature pertaining to this topic and that this database be available to its membership. The individual members could, at their discretion, access it to determine when endodontic files and reamers should be designated SUI in their practice.

## **Management of Infected Root canal Instruments.**

The design of most root canal files and reamers makes their sterilization after use difficult. Most dental jurisdictions mandate that all endodontic instruments be sterilized prior to re-use. This includes a) removal of all tissue and tissue by-products from the instrument surface and b) sterilization by a device that destroys or inactivates all microorganisms and their by-products. Several sterilization

protocols are currently in use; however, their effectiveness remains questionable. The most consistent and effective protocol appears to be one that includes hand and ultrasonic cleaning of instruments immediately after use, followed by processing in an autoclave that is constantly monitored to assure sterility. These methods appear to be effective in eliminating disease transmission caused by most microorganisms found within the root canal system but have been shown to be less effective in eliminating prion protein. However, based upon best current scientific evidence and the very low risk of prion transmission to patients during endodontic treatment in the USA and Canada, the Special Committee on SUI feels that it is not currently warranted for clinicians to change the way in which they select endodontic files and reamers for re-use and sterilization. The Special Committee does recommend that practitioners prepare and sterilize instruments for re-use in accordance with "best evidence" currently available (See references). It also encourages the development of new and innovative methods of sterilization that are simpler and are more efficient in eliminating the prion protein responsible for CJD.

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