

Appendix 2

Summary of Recommendations to Health Canada by the Scientific Advisory Panel on Reprocessing of Medical Devices

1. Reuse of single-use devices (SUDs) shall not be allowed unless it is regulated by Health Canada (HC).
 - If validated evidence for safe reprocessing is demonstrated and compliance with the validated protocol can be assured then reuse of SUDs may be permitted.
 - The validated evidence for safe reprocessing shall include both appropriate level of cleaning, disinfection and sterilization, and documented evidence of maintenance and preservation of device integrity and functionality.
2. Recommend Health Canada send an advisory letter to hospitals and all other health care facilities making interim recommendations on reprocessing of SUDs until some form of regulatory control (either Federal or Provincial/Territorial) is established to ensure patient and staff safety.
3. Recommend Health Canada advise healthcare facilities to follow established national reprocessing standards and guidelines including the following:
 - CSA Healthcare Technology series of standards
 - HC Infection Control Guidelines
 - ISO sterilization standards
4. Recommend Health Canada improve communication to all health care facilities across the continuum of care and include distribution to “frontline” healthcare staff
5. Recommend Health Canada to revisit the medical device licensing rules in an attempt to address a perceived inconsistency between these rules and risk of harm (i.e. majority of surgical instruments do not require medical device licences because they are Class I devices)
6. Recommend Health Canada reconsider constructing a public-access database of medical device problem reports similar to FDA.
7. Recommend Health Canada consider requiring a license for consignment and loaner instrument sets.
8. Recommend Health Canada harmonize the medical device classification system with healthcare, industry and international counterparts.
9. Recommend Health Canada require that manufacturers provide adequate and appropriate reprocessing instructions for all medical devices (e.g. as per CSA/ISO 17664).

10. Recommend Health Canada endorse the following SAP recommendation on the “sterile crud” issue:
 - residual organic material on or in medical devices is unacceptable
 - recommend Health Canada send out a follow-up letter to healthcare facilities and industry clarifying their position on residual organic material
11. Recommend healthcare facilities audit all aspects of medical device reprocessing procedures to ensure compliance with National Standards.
12. Recommend healthcare facilities only purchase or lease medical devices for which they have device-specific, validated reprocessing instructions.
13. Recommend Health Canada obtain the regulatory authority to require the manufacturer of a medical device to conduct a recall or corrective action, where such action is deemed necessary to ensure the safety of the device, or to ensure that the device will function as originally intended by the manufacturer; and require that the action would be taken at no cost to the purchaser of the device, whether the recall or corrective action is undertaken at the manufacturers’ initiative or the Minister’s order.
14. Recommend Health Canada endorse and explore ways and means of bringing the Ontario MOHLTC document “Best Practices for Cleaning, Disinfecting and Sterilization – in all Health Care Setting” to the attention of the Conference of Deputies of Health (within the next 6 months) for their consideration for adoption by all the Provinces and Territories.
15. Recommend Health Canada establish ongoing dialogue between MEDEC, CSA and healthcare representatives to ensure that the issues related to medical device reprocessing and the role of industry are addressed.
16. Recommend that a small working group be struck that includes: representatives of the SAP, MEDEC and CSA to facilitate planning of the initial meeting, to establish the format for ongoing dialogue. The stakeholders that should be kept informed include: healthcare stakeholders, MEDEC, CSA, Health Canada, related professional organizations, and the CMA (surgeons in particular).