



**TITLE: Decision Criteria for Selecting Single Use Devices for Reprocessing: Guidelines and Cost-Effectiveness**

**DATE:** 14 June 2011

## **RESEARCH QUESTIONS**

1. What is the cost-effectiveness of reprocessing single use devices?
2. What are the guidelines or criteria available for the selection of single use devices to be reprocessed by a third party?

## **KEY MESSAGE**

No guidelines or criteria were available for the selection of single use devices to be reprocessed by a third party. Additional references, including some cost information, are available in the appendix.

## **METHODS**

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2011, Issue 4), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic studies and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between Jan 1, 2006 and May 31, 2011. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

**Disclaimer:** The Rapid Response Service is an information service for those involved in planning and providing health care in Canada. Rapid responses are based on a limited literature search and are not comprehensive, systematic reviews. The intent is to provide a list of sources of the best evidence on the topic that CADTH could identify using all reasonable efforts within the time allowed. Rapid responses should be considered along with other types of information and health care considerations. The information included in this response is not intended to replace professional medical advice, nor should it be construed as a recommendation for or against the use of a particular health technology. Readers are also cautioned that a lack of good quality evidence does not necessarily mean a lack of effectiveness particularly in the case of new and emerging health technologies, for which little information can be found, but which may in future prove to be effective. While CADTH has taken care in the preparation of the report to ensure that its contents are accurate, complete and up to date, CADTH does not make any guarantee to that effect. CADTH is not liable for any loss or damages resulting from use of the information in the report.

**Copyright:** This report contains CADTH copyright material and may contain material in which a third party owns copyright. **This report may be used for the purposes of research or private study only.** It may not be copied, posted on a web site, redistributed by email or stored on an electronic system without the prior written permission of CADTH or applicable copyright owner.

**Links:** This report may contain links to other information available on the websites of third parties on the Internet. CADTH does not have control over the content of such sites. Use of third party sites is governed by the owners' own terms and conditions.

## **RESULTS**

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluation, or guidelines were identified regarding the criteria for selecting single use devices to be reprocessed by a third party. Information regarding the safety and effectiveness of reprocessing of single use devices is available in the appendix. Some cost information may be available within these articles. Additional articles that may be of interest are included in the appendix.

## **OVERALL SUMMARY OF FINDINGS**

No literature was identified; therefore no summary pertaining to the guidelines or criteria available for the selection of single use devices to be reprocessed by a third party, or the cost-effectiveness of reprocessing can be provided.

**REFERENCES SUMMARIZED**

**Health technology assessments**

No literature identified.

**Systematic reviews and meta-analyses**

No literature identified.

**Randomized controlled trials**

No literature identified.

**Non-randomized studies**

No literature identified.

**Economic evaluations**

No literature identified.

**Guidelines and recommendations**

No literature identified.

**PREPARED BY:**

Canadian Agency for Drugs and Technologies in Health

Tel: 1-866-898-8439

[www.cadth.ca](http://www.cadth.ca)

**APPENDIX – FURTHER INFORMATION:**

**Systematic reviews and meta-analyses**

*Comparators not specified within the English summary*

1. Martin G, Caron L, Obadia A. La réutilisation du matériel médical à usage unique [Internet]. Montreal: Agence d'évaluation des technologies et des modes d'intervention en santé; 2009. 1-99 p. Report No.: ETMIS 5(2). [cited 2011 May 31]. Available from: [http://www.inesss.qc.ca/fileadmin/doc/aetmis/Rapports/Sterilisation/ETMIS2009\\_Vol5\\_No2.pdf](http://www.inesss.qc.ca/fileadmin/doc/aetmis/Rapports/Sterilisation/ETMIS2009_Vol5_No2.pdf)  
 Summary: reuse of single-use medical devices [Internet]. Montreal: Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS).; 2009. [cited 2011 May 31]. Available from: [http://www.inesss.qc.ca/fileadmin/doc/aetmis/Rapports/Sterilisation/2009\\_02\\_res\\_en.pdf](http://www.inesss.qc.ca/fileadmin/doc/aetmis/Rapports/Sterilisation/2009_02_res_en.pdf)  
*Note: Summary in English. The full report is available in French only.*

*Reprocessed compared to new Single Use Devices*

2. Hailey D, Jacobs P, Ries N, Polisen J, Normandin S, Noorani H, Lafferty S, Gardam M. Reprocessing of single-use medical devices: clinical, economic, and health services impact [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008. (Technology report number 105). [cited 2011 May 31]. Available from: [http://www.cadth.ca/media/pdf/334B\\_Reprocessing-SUDs-Canada-Clinical-Economic\\_tr\\_e.pdf](http://www.cadth.ca/media/pdf/334B_Reprocessing-SUDs-Canada-Clinical-Economic_tr_e.pdf)

**Guidelines and recommendations – methods not specified**

3. Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings [Internet]. Toronto: Ministry of Health and Long-Term Care/Public Health Division/Provincial Infectious Diseases Advisory Committee; 2010. [cited 2011 May 31]. Available from: [http://nurses.ab.ca/carna-admin/Uploads/best\\_practices\\_pidac.pdf](http://nurses.ab.ca/carna-admin/Uploads/best_practices_pidac.pdf)  
*See: Appendix A – Reprocessing Decision Chart, page 75*
4. Reprocessing (cleaning, disinfection & sterilization) critical & semi-critical equipment: a physician toolkit [Internet]. Edmonton: College of Physicians & Surgeons of Alberta; 2010. [cited 2011 May 31]. Available from: [http://www.cpsa.ab.ca/Libraries/Pro/IPAC\\_Reprocessing\\_A\\_Physician\\_Toolkit.pdf](http://www.cpsa.ab.ca/Libraries/Pro/IPAC_Reprocessing_A_Physician_Toolkit.pdf)  
*See: A2, page 6*
5. Best practice guidelines for the cleaning, disinfection and sterilization of medical devices in health authorities [Internet]. Victoria (BC): Ministry of Health, Patient Safety Branch; 2007 Mar. [cited 2011 May 31]. Available from: [http://www.health.gov.bc.ca/library/publications/year/2007/BPGuidelines\\_Cleaning\\_Disinfection\\_Sterilization\\_MedicalDevices.pdf](http://www.health.gov.bc.ca/library/publications/year/2007/BPGuidelines_Cleaning_Disinfection_Sterilization_MedicalDevices.pdf)  
*See: Single-Use Medical Equipment/Devices, page 12 and Appendix A – Reprocessing Decision Chart, page 43*

### Position statements

6. Cause for concern: reuse of single-use medical devices [Internet]. Toronto: MEDEC; 2010. [cited 2011 May 31]. Available from: [http://www.medec.org/webfm\\_send/1216](http://www.medec.org/webfm_send/1216)

### Surveys

7. Polisena J. Reprocessing of single-use medical devices: a national survey of Canadian acute-care hospitals (additional analyses) [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008 Feb 28. [cited 2011 May 31]. Available from: <http://www.cadth.ca/media/pdf/htis/Single%20Use%20Medical%20Devices.pdf>
8. Polisena J. Reprocessing of single-use medical devices: a national survey of Canadian acute-care hospitals (additional analyses) [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008 Feb 28. [cited 2011 May 31]. Available from: <http://www.cadth.ca/media/pdf/htis/Single%20Use%20Medical%20Devices%20II.pdf>  
*Note: includes information regarding types of reprocessed devices*

### Review articles

9. The business case for reprocessing [Internet]. Washington (DC): Association of Medical Device Reprocessors; 2011. [cited 2011 May 31]. Available from: <http://www.amdr.org/wp-content/uploads/2011/04/Business-Case-for-Reprocessing-for-web.pdf>
10. Schroeer P. Reprocessing single-use medical devices: a risky business. Journal of Medical Device Regulation [Internet]. 2011 [cited 2011 May 31];8(1):8-12. Available from: <http://www.unicode.be/data/doc/REUSE%20MEDICAL%20DEVICES%20A%20RISKY%20OBUSINESS.pdf>
11. Polisena J. Reprocessing single-use medical devices: an update of the clinical evidence and an environmental scan of policies in Canada [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2010 Jun 23. (Environmental Scan issue 8). [cited 2011 May 31]. Available from: [http://www.cadth.ca/media/pdf/ES8\\_Reprocessing\\_SUDs\\_e.pdf](http://www.cadth.ca/media/pdf/ES8_Reprocessing_SUDs_e.pdf)
12. Report on the issue of the reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC [Internet]. Brussels: European Commission; 2010 Aug 27. [cited 2011 May 31]. Available from: [http://ec.europa.eu/consumers/sectors/medical-devices/files/pdfdocs/reprocessing\\_report\\_en.pdf](http://ec.europa.eu/consumers/sectors/medical-devices/files/pdfdocs/reprocessing_report_en.pdf)  
*See: 3.5. Economic considerations on the reprocessing of single use medical devices, page 10*
13. Eucomed white paper on the reuse of single use devices [Internet]. Brussels: Eucomed Medical Technology; 2009 Dec 15. [cited 2011 May 31]. Available from: <http://www.eucomed.org/uploads/Press%20Releases/Eucomed%20White%20Paper%20on%20the%20reuse%20of%20single-use%20devices.pdf>  
*See: Economic Aspects, page 23*

14. Bornstein S, Butler J, Kean R. The reprocessing and reuse of single-use medical devices in Newfoundland & Labrador [Internet]. St. John's (NL): Newfoundland and Labrador Centre for Applied Health Research, Memorial University; 2010. [cited 2011 May 31]. Available from: [http://www.nlcahr.mun.ca/research/chrsp/SUDS\\_full\\_web.pdf](http://www.nlcahr.mun.ca/research/chrsp/SUDS_full_web.pdf)
15. Kruger CM. Processing single-use medical devices for use in surgery - importance, status quo and potential. *GMS Krankenhhyg Interdiszip* [Internet]. 2008 [cited 2011 May 31];3(3):Doc21. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2831249>  
[PubMed: PM20204093](#)
16. Single-use device reprocessing [Internet]. Arlington (VA): Practice Greenhealth; 2008. [cited 2011 May 31]. Available from: <http://www.medisiss.com/documents/GreenhealthNewsletter.pdf>
17. Products reprocessed by AMDR's members [Internet]. Washington (DC): Association of Medical Device Reprocessors; 2007. [cited 2011 May 31]. Available from: [http://www.amdr.org/documents/ProductsReprocessedByAMDRsMembers\\_001.pdf](http://www.amdr.org/documents/ProductsReprocessedByAMDRsMembers_001.pdf)
18. Lee RC, Berzins S, Alfieri N. Single-use device reuse risks. *Can J Infect Control*. 2007;22(3):142, 144, 146. [PubMed: PM18044383](#)

#### **Additional references**

19. Association of Medical Device Reprocessors [Internet]. Washington (DC): The Association. Commonly reprocessed medical devices; 2011 [cited 2011 May 31]. Available from: <http://www.amdr.org.php5-15.websitetestlink.com/industry-info/commonly-reprocessed-medical-devices/>
20. Winter MH. Reuse of single-use devices: recognizing the business and risk issues of this new reality [Internet]. Kensington (MD): LNE / G-MED North America, Inc; 2010. [cited 2011 May 31]. Available from: [http://www.lne-america.com/fileadmin/user\\_upload/LNE\\_FILES/PDF/Progress\\_Report\\_-\\_June\\_2010\\_-\\_FNL.pdf](http://www.lne-america.com/fileadmin/user_upload/LNE_FILES/PDF/Progress_Report_-_June_2010_-_FNL.pdf)
21. Executive summary: use of reprocessed single-use medical devices [Internet]. Plymouth Meeting (PA): ECRI Institute; 2009. (Medical Technology 5, vol 3). [cited 2011 May 31]. Available from: [http://aliciakraig.weebly.com/uploads/6/0/6/4/6064219/medtech5\\_reprocessed\\_suds.pdf](http://aliciakraig.weebly.com/uploads/6/0/6/4/6064219/medtech5_reprocessed_suds.pdf)
22. Sloan TW. Safety-cost trade-offs in medical device reuse: a Markov decision process model. *Health Care Manag Sci*. 2007 Feb;10(1):81-93. [PubMed: PM17323656](#)