

Liability Implications for Hospitals of Reprocessing and Reuse of Single-Use Medical Devices

By Pamela C. Spencer

Concern over escalating healthcare costs has led many Canadian hospitals to reprocess and reuse certain medical devices marketed as “disposable” or “for single-use only.” This practice attracted media and public attention in the summer of 2001 with the release of the results of a December 2000 survey by Health Canada which found widespread reuse of single-use devices in acute-care hospitals across Canada.¹ The Health Canada survey also found that the majority of hospitals practicing reprocessing and reuse did not have a reuse committee, nor did they have written reuse protocols in place for the majority of the single-use devices cited in the survey.² In fact, while it appears from the 2000 survey data that the number of reused single-use devices per hospital has increased substantially since the last Canadian survey in 1986, the existence of written protocols has diminished since that study.³

It appears that reprocessing and reuse of disposables is taking place in numerous Canadian hospitals despite manufacturers’ label instructions warning against reuse, and in the absence of recognized data on the safety and effectiveness of reuse, except as regards certain devices and related supplies.⁴ Further, this activity appears to be taking place in the absence of clear guidance and direction from professional associations and other healthcare stakeholders.⁵

Given the level of reprocessing and reuse activity that is reportedly occurring in Canadian hospitals and other healthcare facilities, it seems an appropriate time to consider the legal implications of this practice. To that end, I propose in this article to overview the various theories of legal liability for hospitals engaged in the reprocessing and reuse of disposables,

and then suggest a framework for action to limit exposure to any such liability.

Regulation of Medical Device Reprocessing and Reuse

The starting point for our discussion is an overview of how reprocessing and reuse of disposables is regulated in Canada.

Canada’s *Food and Drugs Act* and *Medical Devices Regulations* prescribe legal requirements for manufacturers of medical devices and regulate the sale, importation and advertising of these products. The *Medical Devices Regulations* define a manufacturer to mean “a person who **sells** a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person...” [Emphasis added] Because the definition hinges on whether the device is sold, the Medical Devices Bureau of Health Canada has taken the position that hospitals which engage in reprocessing and reuse are not device manufacturers within the meaning of the *Regulations* as the hospital does not “sell” the device nor does it distribute the device under its own name or trademark. The one possible exception to this position is the case of devices that have been permanently implanted in a patient. The Bureau has also taken the position that neither the *Food and Drugs Act* nor the *Medical Devices Regulations* prohibit the “off-label use” of a device, which occurs when the disposable is reused contrary to the manufacturer’s instructions.

Based on its interpretation of the legislation, Health Canada has, to date, taken the position that it does not have the authority to regulate the use of medical devices in a clinical environment and, by extension, the reuse of disposables. The use and reuse of med-

ical devices is thus controlled by provincial laws and medical licensing bodies.

It should be noted that, in contrast to Health Canada’s position, the U.S. Food and Drug Administration (FDA), working within the context of the U.S. regulatory environment for medical device oversight, has taken the position that hospitals and third-parties engaged in reprocessing single-use devices will be subject to all the regulatory requirements currently applicable to original equipment manufacturers, including pre-market submission requirements.⁸ While this action on the part of the FDA may eventually motivate a change in the regulatory environment in Canada as regards reuse activity, from a risk management point of view, it should be noted that the FDA announced this stepped-up oversight while, at the same time, acknowledging that there is a lack of clear data that directly links injuries to reuse.⁹ On this point, the U.S. General Accounting Office in its Report to Congressional Requesters on the safety of single-use device reprocessing in the United States, concluded as follows:

“While the evidence shows that carefully controlled reprocessing of some SUDs [single-use devices] is safe, it is also clear that some SUDs cannot be safely reprocessed, procedures for safe reprocessing are not always followed, and the limitations of the information available about SUD reprocessing argue for monitoring of the practice.”¹⁰

The FDA’s stepped-up oversight of medical device reprocessing should be understood in the context of these comments.

In Canada, concerns over the safety of reused disposables prompted the

Manitoba Ministry of Health in February 1998 to institute a ban of critical disposables in Manitoba health care facilities. In response to this ban, the Deputy Ministers of Health instructed its Advisory Committee on Health Safety (ACHS) to set up a working group to consider the development of uniform policies to regulate the reuse of disposables. While the results of a commissioned survey on reuse practices were presented to the ACHS in May, 2001, to date, the ACHS has not formally responded to the survey results. It has however written to the Canadian Council on Health Services Accreditation to suggest inclusion of inspection of reprocessing and reuse facilities as part of the hospital accreditation process, which is the practice in the U.S.

Notwithstanding the lack of a clear regulatory mandate to oversee reprocessing and reuse activity within hospitals, Health Canada has been under pressure from device manufacturers, hospitals and other healthcare stakeholders to take action to standardize national and provincial policies on reuse. In response to this pressure, Health Canada has advised that it is re-examining its authority to regulate reuse practices and is developing options for policies and/or regulatory policy in this area.¹¹ Hospital reproducers will need to keep an eye on any developments initiated by Health Canada in this area.

Theories of Liability for Reprocessing and Reuse

This discussion of theories of legal liability for reprocessing and reuse must be prefaced with the disclaimer that, as there has been no reported case on this issue in Canada, my analysis, while reasonable and based on established trends in the case law, is ultimately speculative. The definitive word on the liability of hospital reproducers will have to come from the courts when a case on this issue presents itself.

With that disclaimer out of the way, we can move on to consider the theories of legal liability for hospital reprocessing

and reuse activity. It should be noted that while the focus of this article is on liability of hospitals for reuse activity, in any action alleging damage caused by reused single-use devices, other parties, including the original device manufacturer, distributors and hospital physicians engaged in reuse activity, may be added to the action. Additionally, even if the plaintiff does not join some or all of these parties as defendants, members of the distribution chain may initiate indemnification or contribution action against other chain members.

of a device in reuse, or infection or other adverse reaction attributable to the reprocessing of the reused device, then the hospital could face liability for breach of its duty to provide safe facilities.

In assessing whether a hospital's corporate actions are negligent or contributorily negligent in an action relating to reuse activity, the hospital will be held to a reasonable standard of care. As such, a hospital may be found liable for failing to take reasonable measures to guard against foreseeable risks. In considering the hospital's

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(A) NEGLIGENCE

Injuries resulting from inadequate or inappropriate reprocessing may result in litigation under tort claims of negligence. To establish negligence, the plaintiff generally must demonstrate that:

- (1) the defendant owed the plaintiff a duty of care;
- (2) the defendant breached the duty of care;
- (3) the plaintiff was injured; and
- (4) the defendant's breach of duty proximately caused the plaintiff's injury.

A negligence action against a hospital for reuse activity may be based on either a claim of corporate or institutional negligence or on the basis of vicarious liability for the actions of the hospital's employees.

With respect to corporate liability, it is an established principle under Canadian law that hospitals owe a duty of care to patients to provide proper and adequate facilities and equipment so as to reasonably ensure patients' safety.¹² This corporate duty of care also extends to proper maintenance of these facilities and equipment, which would include procedures for handling, sterilization and reuse of disposables. Therefore, if a patient is injured by reason of the failure

conduct in a reuse action, the court will consider the steps taken by the hospital to ensure that appropriate protocols are developed and followed in the case of each single-use device that is to be reused, to ensure that reuse of the device is safe and presents no increased risk of injury or harm to the patient beyond that inherent in the initial use.

In assessing whether a hospital has met the standard of care in reusing a single-use device, the court may look at the standards in place at other comparable institutions, as well as at existing published clinical research data on the safety of the device in question. If the hospital can show that reasonable protocols have been developed and followed to ensure the safety of reused disposables, then the hospital may be able to avoid legal liability for alleged corporate negligence.

On the specific issue of the hospital's duty to ensure that its policies are adhered to, in a recent case, the New Brunswick Court of Appeal, found a hospital liable in negligence for failing to adopt adequate measures to ensure that its medical staff would follow an internal hospital policy dealing with physician consultation in the emergency department.¹³ The court found

the hospital liable despite the fact that the policy at issue had not been formally adopted as a by-law or a regulation of the Hospital. The efforts of the hospital to ensure that its employees and its medical staff follow hospital policy regarding reprocessing and ensure may therefore be at issue in any claim alleging negligence with respect to reused disposables.

With respect to the data which a hospital may advance in support of the safety of a reused disposable, it is important to underline that while accepted research data may exist in support of the reuse of the disposable in question, the hospital will also be required at trial to establish that it was able to duplicate within its facility the accepted sterilization and other reprocessing practices for the disposable. As such, the hospital will have to produce data in support of its internal validation of the safety of its own reprocessing and sterilization processes for the reused disposable. The documentation by the hospital of this data is therefore crucial.

Separate from a hospital's liability for its negligent institutional actions, a hospital may also be held vicariously liable for the negligence of its employees. That is, the hospital may be held vicariously liable for a tort committed by an employee acting within the scope of his or her employment. The employee's negligence may be imputed to the hospital, even if the hospital exercised the utmost care in selecting employees qualified in device reprocessing, or in establishing appropriate reprocessing protocols. The hospital may also be liable for the failure of an employee to inspect a reprocessed device prior to reuse. The imputation of vicarious liability to an employer is based on social and policy considerations, the discussion of which is beyond the scope of this article.¹⁴

(B) INFORMED CONSENT

It is accepted law in Canada that healthcare providers must obtain the informed consent of patients prior to carrying out medical treatment. While

this duty rests principally with the practitioner who plans to carry out the proposed treatment, there is case law which suggests that hospitals have an independent non-delegable duty to ensure that informed consent is obtained from patients prior to medical treatment.¹⁵ While the non-delegable nature of this duty is open to comment,¹⁶ hospitals should operate on the basis that they have a duty to put systems in place, such as protocols and proper procedures, designed to promote informed consent as well as a duty to ensure that these systems are followed. The failure on the part of the hospital to implement systems to ensure that informed consent is obtained and to ensure compliance with these systems may result in a finding of negligence against a hospital in a given action.

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Whether device reprocessing must be disclosed to a patient as part of the informed consent process will depend on the nature of the risk associated with reuse. If the hospital can establish to the court through scientific data or expert opinion that there is no increase in the level of risk to the patient with a reused device, then it is reasonable to proceed on the basis that there is no need to obtain specific informed consent to the use of the reused device. Although it would be possible for a patient to argue that, the fact of whether medical equipment to be used in his treatment was reused or not was of material importance to him, in the absence of any material increase in clinical risk with the reused device, it is unlikely that a court would find that the treating physician or the hospital had a duty to disclose that a disposable device was intended to be used in the course of treatment. That being said, the lack of full and frank disclosure may raise ethical concerns for the hos-

pital and its physicians in terms of their commitment to principles of patient autonomy.

While there may not be a legal duty on the part of a hospital to disclose to a patient that a particular device is being reused where the hospital has determined that there is no materially increased risk in the use of the reused device, it does not follow that a hospital could mislead a patient where a direct question regarding reuse is raised by a patient. It is not unreasonable to expect that as patients become more aware that disposables are being reused, certain patients may enquire as to the hospital's reuse practices and may refuse to consent to the use of reused disposables as part of their treatment. Where a patient informs the treating physician that he or she refuses

to allow the use of a reprocessed device in the patient's treatment, that wish must be honoured. The patient's refusal must then be transmitted to all of the appropriate persons at the hospital where the procedure is to be performed. In addition, in anticipation of potential patient refusals and potential litigation surrounding its reuse practices, hospital reprocessors will need to ensure that their labelling practices and inventory management practices are designed so as to permit physicians to determine that no reprocessed devices will be used in a particular procedure. The logistics component of using reprocessed devices is an area that may be overlooked by hospitals in designing reuse protocols, but it is an area that merits specific attention.

(C) LIABILITY TO WORKERS ENGAGED IN REPROCESSING

There is an argument that reprocessing of single-use devices raises occupational safety and health concerns on the part of the hospital on the basis that

reprocessing may increase the exposure of workers to blood-borne pathogens or toxic disinfectants or both. Such injuries or exposure may result in liability of the hospital to its employees under provincial occupational health and safety legislation.

The fact is however, that while reprocessing of disposables does create additional opportunities for hospital workers to be exposed to infection, hospital employees are regularly employed in sterilizing and reprocessing reusable devices. Therefore, the real issue for the hospital is in ensuring that safe sterilization and reprocessing procedures and practices are in place to ensure worker safety, regardless of whether the worker is engaged in reprocessing a reusable or a disposable device. The safety concerns inherent in reprocessing should be addressed in the hospital's occupational health and safety standards within the context of the province's occupational health and safety legislation. As well, by bringing in uniform hospital-wide reuse policies as discussed below, the practice of allowing non-trained employees to engage in the reprocessing of disposables on an ad hoc basis can be corrected.

(D) PATENT AND TRADEMARK INFRINGEMENT ISSUES

While there is no reported case in Canada on this issue, there is one reported U.S. case in which the appellate court recognized that a manufacturer may be able to assert an action for patent infringement and inducement to infringe against a reprocessor of medical devices. There is also the possibility that a manufacturer could bring an action against a hospital reprocessor on the basis of trademark infringement.

Developing a Reuse Program in Your Hospital

As discussed above, hospitals engaged in reprocessing are exposed to liability under various legal theories in actions alleging injury caused by the reuse of single-use devices. Existing hospital reproducers and hospitals contem-

plating the reuse of disposables should therefore consider taking steps to reduce their potential liability. While there is no certainty that by following the steps suggested below that a hospital will avoid liability in a reuse action, adherence to these steps would likely be considered favourably by the courts.

1. The first step is for senior management to commit to the development of an internal policy on reuse, even if it ends up being a statement forbidding reuse practices. A uniform, hospital-wide policy should ensure that reuse decisions are made on a consistent and rational basis throughout the institution. Once developed, the hospital's reuse policy should receive Board approval and senior management should implement adequate measures to ensure that it is adhered to internally.
2. A multidisciplinary Reuse Committee should be established to lead the development of the hospital's reuse program. Since the final decision to reuse a given disposable will be based on many factors, including economic, clinical and risk-management factors, the Committee should bring together the necessary expertise of representatives from biomechanics, infection control, materials management and finance in order to assess the safety of the reuse of individual disposables. The hospital's risk manager and in-house counsel may also be valuable Committee members.
3. In its Terms of Reference, the Reuse Committee should be charged with identifying the information required and the approval sequence from individual departments to the Committee for devices being proposed for reuse. The required information can be captured in an Impact Analysis Worksheet to be completed by the head of the department proposing the reuse of a disposable and submitted to the Reuse Committee for consideration. The Worksheet should have attached to it copies of actual reports

that document evidence as to the safety of reuse of the device.

4. In making its determination to approve the reuse of a particular device, the Reuse Committee will first consider the data analyzing the clinical assessment of risk to the patient from reuse of the disposable. Unless the Committee is satisfied, based on the validated data presented to it, that there is no material increase in the level of risk to the patient with a reused device beyond the risks inherent in the initial use, then the Committee should refuse to approve of the reuse request. Establishing the clinical safety of each device that is proposed to be reused is the threshold question for the Committee. The clinical safety data should also establish the expected life of the disposable, i.e., the number of times the disposable may be safely reprocessed before it should be disposed of.
5. Assuming that the Reuse Committee is satisfied with the risk assessment of reuse, the decision to approve the reuse of a given disposable should be based on an analysis of the following factors:
 - i) have safe and effective cleaning and sterilization procedures been validated and implemented?
 - ii) what procedures are in place to ensure that the cleaning and sterilization processes are properly documented?

With respect to sterilization procedures, the FDA Reuse Guidelines requires that hospital reproducers maintain documentation to show that the sterilization equipment has been installed correctly and operates as intended. Hospital reproducers are also required to maintain documentation showing that the sterilization process has been validated as being effective in achieving sterility without adversely affecting the devices, as well as documentation for process control procedures and data to prove that for each run the specifi-

cations for sterilization parameters have been met.

iii) have employees received proper training in reprocessing?

iv) is there financial data to support that the reprocessing and reuse of the disposable is cost-effective? Since the rationale for the reuse of disposables is to save money, the department proposing reuse should include a cost comparison of the total costs involved in reprocessing the disposable as against the costs of buying and disposing of replacement disposables. Reprocessing costs for a given disposable may include costs associated with employee training, capital equipment requirements, equipment maintenance and upgrading, sterilization, storage, record keeping for all reprocessed devices, and quality assurance. Reprocessing may also result in increased insurance or legal costs. The financial data may establish that it is not cost-effective for smaller hospitals to reprocess their disposables.

v) are there procedures in place to ensure that new data establishing the safety of the device will be received and presented to the Reuse Committee in a timely fashion?

6. As part of its ongoing oversight of the hospital's reuse practices, the Reuse Committee should periodically review and update its reuse policies and procedures to ensure adherence to any new guidelines or recommendations at the technical level, as well as any regulatory changes. The Committee may also consider implementing pre-use inspections.
7. Finally, the Reuse Committee should the implications of outsourcing the reprocessing of disposables to third party device reprocessors. Given the certification process now in place for U.S. third party reprocessors of medical devices, there may be an advantage to hospitals in outsourcing this activity, particularly now as U.S.

reprocessors express an interest in the Canadian marketplace.

Conclusion

Hospitals engaged in the reprocessing and reuse of disposables are exposed to legal liability under various legal theories, and should therefore take steps with the aim of reducing their exposure. While there is no guarantee that by taking the steps suggested in this article hospitals will avoid liability in a reuse action, these steps could go a long way in that regard.

Resource List

1. Canadian Healthcare Association, *The Reuse of Single-Use Medical Devices, Guidelines for Healthcare Facilities*. CHA Press, Ottawa, 1996.
2. The FDA has guidance documents that apply generally to all types of manufacturing processes including sterilization. For online access to this documentation, see U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, *Frequently-Asked Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff*. Issued July 6, 2001. Available at <http://www.fda.gov/cdrh/ohip/guidance/1333.html>.

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Footnotes

1. Health Canada, *Infectious Diseases News Brief*, August 17, 2001. Available at http://www.hc-sc.gc.ca/pphb-dgspsp/bid-bmi/dsd-dsm/nb-ab/2001/nb3301_e.html.
2. M.A. Miller, D. Gravel and S. Paton, Canada *Communicable Disease Report*, Volume 27-23, December 1, 2001. Available at <http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/01vol27/dr2723ea.html>.

3. Ibid.

4. U.S. General Accounting Office Report entitled "Single-Use Medical Devices: Little Available Evidence of Harm from Reuse, but Oversight Warranted," June 2000. Available at <http://www.gao.gov/new.items/he00123.pdf>.

5. Canadian Healthcare Association, *The Reuse of Single-Use Medical Devices, Guidelines for Healthcare Facilities*. CHA Press, Ottawa, 1996, at pages 9-10.

6. R.S. 1985, c. F-27.

7. SOR/98-282.

8. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, *Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third-Parties and Hospitals*. Issued August 14, 2000.

9. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Notice re Reuse of Single Use Devices, at <http://www.fda.gov/cdrh/reuse/index.shtml>

10. U.S. General Accounting Office Report, "Single-Use Medical Devices: Little Available Evidence of Harm from Reuse, but Oversight Warranted," *op. cit.*, at page 16.

11. Philip Neufeld, Manager, Device Surveillance Division for the Medical Devices Bureau, Health Canada. "Reuse in Canada: Practices, Guidelines and Regulations," paper presented at the Ontario Hospital Association Conference, "Reuse of Single Use Medical Devices: A Health Care Dilemma," Toronto, Ontario, February 1, 2002.

12. E. Picard and G. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3rd edn., (Toronto: Carswell Thomson Professional Publishing, 1996) at page 379. See also *Bartlett v. Children's Hospital Corp.* (1983), 40 Nfld. & P.E.I.R. 88 (Nfld. T.D.), rev'd (1985), 55 Nfld. & P.E.I.R. 350 (Nfld. C.A.), and *Briffett v. Gander & District Hospital Board*, (1992), 326 A.P.R. 271 (Nfld. T.D.), aff'd (1996), 428 A.P.R. 271 (Nfld. C.A.).

13. *Comeau v. Saint John Regional Hospital*, [2001] N.B.J. No. 450.

14. See E. Picard and G. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3rd edn., *op. cit.*, at pages 353-356 for a discussion of these policy considerations.

15. *Lachambre v. Nair* [1989] 2 W.W.R. 749 (Sask. Q.B.).

16. See E. Picard and G. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3rd edn., *op. cit.*, at pages 146-147.

17. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, *Frequently-Asked Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff*. Available online at <http://www.fda.gov/cdrh/ohip/guidance/1333.html>. Issued July 6, 2001.