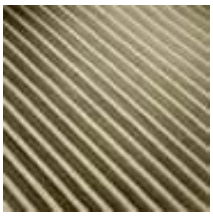

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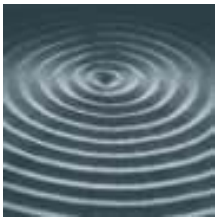

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REFURBISHED MEDICAL DEVICES

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REFURBISHED MEDICAL DEVICES

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INTRODUCTION

Canadians consume $5 billion in medical devices annually.[1] There has been a significant increase in the reuse of devices through re-sterilization and/or refurbishing, mostly due to the financial constraints facing hospitals. The types of devices that are being re-used in Canada to day include simple surgical instruments such as microscalpels and operating room clamps; equipment that includes respiratory breathing circuits, tracheal tubes and catheters and; equipment to be left inside patient such as cardiac pacemakers.[2] Such reuse inevitably gives rise to significant concerns for risk and consequent liability. There are two major concerns: i) risk of infection and ii) risk of malfunction.

Reuse of devices related to risk of infection and consequent sterilization is typically classified as:

1. Total reuse. A device is thoroughly cleaned and sterilized by the same hospital, a second hospital or a manufacturing facility for use by the same or a second patient.

2. Re-sterilization. Further sterilization of a product that was sterile when received from the manufacturer. The purpose is either to include an already sterile product in a larger package or to ensure sterility because the sterilization guarantee date has expired.

3. Reprocessing. A package opened in error and essentially unused is repackaged and desterilized.[3]

Further classification for such devices relates to cross contamination between patients:

1. Critical. The device penetrates sterile body parts such as the blood system.

2. Semicritical. The device touches a mucous membrane, for example respiratory equipment.

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[1] *Report of the Auditor General of Canada*, [Ottawa: Queen's Printer, 2004], at para 2.15

[2] Canadian Healthcare Association, *The Re-use of Single use Medical Devices: Guidelines for Healthcare Facilities*, [Ottawa: Canadian Healthcare Association, 1996] at 7.

[3] *Ibid* at 4.

3. Noncritical. The device does not contact the patient or contacts only the intact skin.[4]

The Canadian Healthcare Association notes that there is no classification currently used to address the concern for malfunction.[5] The refurbish of medical devices can be done by the facility which retrieves them, the facility which is intending to reuse them or a third party refurbishing the device, which usually, is not the original manufacturer. There are no reprocessing companies in Canada although hospitals refurbish when they re-sterilize.

STATUTORY PROVISIONS

Federal

The current Medical Devices Program in Canada, managed by Health Canada, provides for the management of risk before products are made available for sale, through quality systems management and pre-market activities, However, Health Canada has taken only limited action on the re-use of devices sold initially for single use.[6]

The Food and Drugs Act, S.C. 1993, c.34, s.73 provides Regulations for Medical Devices.[7] These regulate the importation of a medical device for sale or use on individuals (s.2(b)) but do not address the reuse of refurbished devices. Under these regulations a manufacturer must obtain a licence for sale from Health Canada before they may place a device for sale in Canada. This product must be validated for safety by the manufacturer, only for its intended use. Therefore, the manufacturer does not design or test a product for reuse. Health Canada does not regulate the reuse. There is no requirement for a hospital or a third party reprocessor to validate the safety of the reuse;[8] however, the Medical Devices Bureau has taken the position that this Act does not prohibit the reuse of devices, either.

Nevertheless, as concern grows, Health Canada is beginning to express interest in becoming involved in the reuse of these devices. In a letter dated July 2004, to hospitals and national and

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[4] *Ibid* at 5.
[5] *Ibid.*
[6] *Ibid* at para 2.4.
[7] F-27-SOR/98-282.
[8] MEDEC, *The Reuse of Single Use Medical Devices*: *A Position Paper*, [Toronto: MEDEC, 2004] at 4.

provincial health associations, Health Canada indicated that the federal government recognizes that

> "...patient care [has] traditionally been the responsibility of Provincial and Territorial health ministries and hospital boards. Consequently, Canada's Food and Drug Act and Medical Devices Regulations have not addressed the way in which a health facility uses, maintains or sterilizes medical devices. Furthermore, the Regulations do not address the situation in which a third party reprocesses devices belonging to a hospital and returns them to that facility for reuse.
>
> However, Health Canada has the mandate to protect Canadians against risks to health and the spreading of disease. Health Canada is therefore reviewing its authority to establish regulations governing the safety of reprocessing SUD's" [single use devices].

Thus, although Health Canada sees the responsibility and consequent liability resting with the facility which chooses to use a refurbished product, it is acknowledging that there might be a role for the federal government to establish some regulation of this increasingly controversial practise. Nevertheless, there is no imminent ban on reuse.

Provincial

The only statutory provision in Ontario that specifies the use of devices is the *Public Hospitals Act*, R.S.O. 1990 c. P.40 , Regulation 965 s.4(1)(d)(ii) which requires that a board shall pass by laws for the safe use of substances, equipment and medical devices in the hospital. This however, is relevant only to the occupational health and safety procedures. It is not addressing patient safety. Nevertheless, under that Act the Board does have a responsibility for providing for the safe care and treatment for patients which would include the provision and use of medical devices.

Some provinces do regulate the reuse of medical devices; for example, Quebec guidelines indicate that cardiac catheters should not be reused if they have come in contact with a vector for Creutzfeldt-Jakob Disease and Manitoba has imposed a ban on the reuse of critical disposable medical devices.

COMMON LAW

There is no common law on reuse other than a recent case of a $27.5 million settlement of a case involving a Toronto neurologist whose patients developed hepatitis B from contaminated electroencephalography electrodes.[9] This case recognizes the well established principle that the facility (in this case a practitioner's office) has a responsibility to provide and use safe equipment. The satisfactory sterilization of such equipment is not a new issue but this involved the sterilization of disposable electrodes.

The most renowned case relative to medical devices is *Hollis v. Dow Corning Corp.*, heard by the Supreme Court of Canada.[10] This case regarding breast implants, confirms the 'learned intermediary rule' which is that a manufacturer may fulfill its 'duty to warn' responsibility by informing a 'learned intermediary' for example, a physician. Once informed, the responsibility becomes that of the intermediary to inform the patient of any risk relevant to the use of the device. Although this does not specifically address a reused device, the principle is certainly transferable.[11]

OTHER JURISDICTIONS AND OTHER AGENCIES

United States of America[12]

The USA does regulate reuse. It imposes the same quality systems on hospitals and third party reprocessors as is imposed on manufacturers.

United Kingdom[13]

There is a Medical Devices Agency which states that reuse of single use devices is not permitted.

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[9] *Andrew v. Wilson* (1999), 175 D.L.R. (4th) 409.
[10] 129 D.L.R. (4th) 609.
[11] *Ibid* at para 27.
[12] Ontario Hospital Association, *Reuse in Canada: Practices, Guidelines and Regulations*, [Toronto: O.H.A. 2002] at 5.
[13] *Ibid.*

Manufacturers[14]

Predictably, MEDEC (Medical Devices Canada) does not condone reuse for any reason.

Ontario Hospital Association[15]

In a position statement in 2004, the O.H.A. states:

> "The OHA recommends that Ontario Hospitals do not reprocess critical and semi critical SUMeD [single use medical devices] that are meant to be used in sterile body sites or come in contact with mucous membranes…The OHA does support reprocessing of SUMeD by Canadian Regulated Third Party Reprocessors that are legislated by Health Canada…"

Canadian Healthcare Association

This organization has not taken a position. It did publish guidelines in 1996 for a framework that can be used by an organization to make an informed decision on the reuse of medical devices.[16]

INSTITUTIONAL AND PROFESSIONAL LIABILITY

Ultimate Responsibility

Institutional and professional liability is based on a duty of care to each and every patient to provide proper and adequate facilities and equipment. A failure of a device, either for lack of sterilization or for a malfunction could render the hospital, and the physician involved, liable in negligence for a breach of its duty of care. Only if the physician was not aware at all that the device was reused might he or she carry no liability for a misadventure with such a device. The facility and/or the professional have a responsibility to take reasonable steps against foreseeable risks, therefore, one is responsible for ensuring that the products and equipment are selected, prepared (as necessary) and utilized according to appropriate standards. Included in those standards are i) any statutory regulations, ii) industry standards i.e. practices in comparable facilities, and iii) the manufacturers' recommendations. The court would look at the fact that there are no regulations regarding reuse, whether there are manufacturers' instructions regarding

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[14] *Ibid.*

[15] *Ibid* (executive summary).

[16] *Supra* note 2 at 57.

reuse and if not, would then place the liability for any failures to safeguard the patient squarely with the hospital.

The potential liabilities are as follows:

- A product liability in respect of the hospital's obligation to provide a device which will properly perform as per its intended use as a single use device
- A liability arising out of the initial decision as to whether the device is appropriate to reprocess
- A potential liability in respect of its selection of a third party reprocessing company on the basis of whether it knew or ought to have known that the company was not competent and skilled to undertake such reprocessing
- A liability for the quality and standards employed in undertaking the reprocessing

One can only avoid or reduce these liabilities if it demonstrates that it exercised reasonable care when reusing devices. This would include:

1. Obtaining from the manufacturer specific information about the dangers of reusing a device. This would include particulars to retain the physical integrity of the product.

2. Establishing protocols for the preparation and safe use of the device.

3. Ensuring that staff is adequately trained in these protocols.

4. Obtaining warranties from third party reprocessors that the product is sterile and/or functional to a standard necessary and expected for the intended use. (See further discussion below).

5. Determining that the product is indeed safe for use after refurbishing. This is a very high standard for a hospital to meet.

Consent

One of the most controversial issues is whether the patient should be informed that the devices used for the procedure are reused. Informed consent under the *Health Care Consent Act* and within well established case law includes a disclosure and discussion of material risks. These are

either common occurring risks or an unusual risk that nevertheless, would have a significant impact on this patient.

In simple re-sterilization matters, the courts would support the expectation of the plaintiff that any equipment used to execute a procedure would be properly sterilized and discussion of this matter with consequent express consent likely would not be expected. Similarly, if reuse does not result in any increase in a significant risk of any nature, for example the hospital has put adequate protocols in place to ensure safety, it would not be expected that the hospital would reveal to the patient that the product is being reused. Of course, it does not follow that a hospital should deliberately mislead a patient if a direct question is posed about such products. Nevertheless, if there is a material risk from reuse, even from re-sterilization, the court would uphold the claim that the risks should have been disclosed and consent obtained for the use of a refurbished device. The principle applied by the courts is the 'reasonableness' test. What would a reasonable patient, in those circumstances, expect to be told in order to make an informed decision?

Third Party Reprocessing

In the first instance, as noted above, the hospital carries liability for the product as purchaser and owner of the device. This makes the hospital liable for the performance of the device. The question then is raised – "Can the hospital obtain any indemnification from the reprocessor in the same way as they might from an initial purchase of a product from a manufacturer?"

As noted above, there is no definitive case yet which determines the liability of hospitals and third party reprocessors for the reuse of a single use medical device. Nevertheless, it is a common practice in Canada to enter into service agreements with manufacturers which hold the purchaser harmless for any product malfunction. In other words, it is not unusual for a manufacturer to hold harmless a contracting party for failure or negligence on the part of manufacturer. Thus, there is settled law that there is liability for a manufacturer selling a product. There is some law in Canada at the Supreme Court of Canada level, also not unusual in the United States, that a supplier of goods has an implicit warranty for the product's quality and fitness for the purpose for which it is intended.[17] This liability exists even in the absence of

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[17] *ter Neuzen v. Korn*, [1995] 3 S.C.R. 674.

negligence on the part of the manufacturer or the hospital and includes situations where the seller was not aware of a defect in the product. This is void, of course, if there is an explicit exclusion for any such warranty. This liability is applied to the first use of a product purchased by the hospital directly from a manufacturer. It is not likely to be upheld against the manufacturer when the product is 'interfered with' by reprocessing. However, one aspect that is not settled is whether the manufacturer has a duty to warn that the product should not be reused. Most products do not yet carry that warning. Some legal opinion suggest that the manufacturer does have a duty to warn and maybe to implement a 'self destruct' feature on a product to prevent its reuse.[18]

What is the application to third party reprocessors, then? The principle of manufacturer's liability was evolved from commercial manufacturing and may not be applicable to not-for-profit facilities which are providing health care to the public. Such refurbishing by another facility may not constitute a sale for this purpose but rather it would be a service. The more the situation moves away from a commercial contract of sale, the less likely this principle will apply. Thus, it is unlikely to apply the principle of implied warranty to a third party reprocessor. Further, American law has shown that the incidental supply of goods (as in refurbishing), provided for medical treatment does not attract strict liability as in a direct sale of a product.[19] This reasoning was followed by the British Columbia Court of Appeal in *ter Neuzen* but not followed in Ontario in *Pitman v. Bain.*[20] In no way does this prevent one from establishing a service contract with a third party processor, holding the hospital or the physician harmless for any negligence or malfunction of the refurbished device. Any facility contemplating the use of such a service should proceed only with such a contract in place.

One factor that the hospital should require therefore, is that a reprocessor maintains adequate insurance for indemnifying the hospital. The hospital should require proof of such insurance and that the specific hospital is named as an insured under the policy. Further, this insurance should be applicable in the jurisdiction i.e. Ontario. This is imperative when dealing with American reprocessing firms.

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[18] *Supra* note 8 at 14.

[19] *Perlmutter v. Beth David Hospital* (1954), 123 N.E. 2d 792.

[20] (1994), 19 C.C.L.T. (2d) 1.

CONCLUSION

The decision to refurbish and reuse medical devices is highly controversial although understandable, given the increasing financial pressures on hospitals. There are no federal legislated standards regarding the reuse of medical devices although Health Canada is considering whether it has a responsibility to regulate reuse; nor are there any in Ontario. Therefore a hospital in Ontario must look to the common laws of tort and contract to establish an understanding of liability. Under tort law the hospital has a legal duty of care to its patients to provide a safe environment within the standards of the industry. The hospital is directly liable for the decision to reuse a device, just as it is liable for the decision to use any product. It is usual for a hospital to understand when a specific device is intended for single use; and the manufacturer provides directions for the use of the product. Without the manufacturers' express directions for reuse, which are not usually found on the labelling, the hospital is unlikely to be indemnified by the original manufacturer should the hospital reuse a device. This places liability squarely with the hospital. The next question then becomes, is it possible to obtain indemnification from the reprocessing facility? This is not yet tested in the courts therefore, if it is to be possible, the hospital should pursue it through contract with the reprocessor. In such a contract, the hospital should ensure that the reprocessor has adequate insurance for indemnification which acknowledges the jurisdiction of Ontario, especially if the reprocessor is located in the United States.

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