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What is the evidence on the safety and effectiveness of the reuse of medical devices labelled as single-use only?

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LEVEL OF EVIDENCE CONSIDERED IN TECH BRIEFS

Tech Briefs are rapidly produced assessments of the *best available evidence* for a topic of highly limited scope. They are less rigorous than systematic reviews. Best evidence is indicated by research designs which are least susceptible to bias according to the National Health and Medical Research Council's (NHMRC) criteria (see **Appendix 1**).

Where methodologically acceptable and applicable, appraised evidence is limited to systematic reviews, meta-analyses, evidence-based clinical practice guidelines, health technology assessments and randomised controlled trials (RCTs). Where not available, poorer quality evidence may be considered.

CONFLICT OF INTEREST

None.

SECTION 1: SUMMARY OVERVIEW ON THE SAFETY AND EFFECTIVENESS OF THE REUSE OF SINGLE-USE MEDICAL DEVICES

The review updates the New Zealand Ministry of Health on the way in which other health authorities are regulating the reuse of medical devices labelled as single-use (SUD) and provides evidence on the safety and effectiveness of such practices from the published literature. The review provides background information for deciding whether or not to implement a similar policy to Australia on the reprocessing and reuse of SUDs or whether an alternative policy should be considered. Additional aspects such as a cost-benefit analysis on the implementation and non-implementation of this policy are to be undertaken by organisations other than NZHTA.

Single-use medical devices (SUDs) are invaluable in ensuring device function, sterility, and prevention of cross-infection. The popularity of reprocessing and reuse of SUDs has primarily arisen from the cost saving and environmental benefits of such practices, but also from a relative lack of safety data and has led to the development of formal reprocessing and reuse policies.

Hospitals in New Zealand follow the Australian and New Zealand standards on reusable and non-reusable medical devices and surgical equipment cleaning, disinfecting and sterilisation. Although it is recommended that used SUDs be discarded and that reuse involves patient risk, local hospital policies and procedures apply. All hospitals have their own reuse committees, policies and procedures in place. Any reprocessing and reuse of SUDs is only permitted with compliance to these standards. Manufacturers do not recommend the reuse of SUDs and this is not endorsed or permitted, however some hospitals do not follow the manufacturer's recommendations.

The policy statements on reuse from other international health authorities tend to be cautionary with a call for more research, quality control mechanisms and written protocols and guidelines for facilities involved in reprocessing and reuse. The FDA in the United States has the most stringent regulations and has set a precedent that allows for regulated reprocessing of SUDs. The EU on the other hand has no uniform policy. The Australian TGA position is similar to that of the FDA, but these regulations are yet to be implemented. In Canada, there are no regulations governing the reuse of SUDs.

The evidence for the safety and effectiveness of reusing SUDs is anecdotal with few studies evaluating outcomes directly related to patients. There is a lack of data on patient exposure to cross-infection, loss of device functionality, and resulting adverse patient outcomes. Much of the literature is set in laboratory contexts evaluating surrogate outcomes such as contamination and device integrity, so the overall evidence is indirect. The literature often forms more of a theoretical basis for these concerns than any firm scientific evidence.

There are conflicting results from the studies reviewed. Some studies conclude that the reuse of SUDs is potentially safe and effective with strict reprocessing protocols and standards, while others do not recommend reprocessing and reuse because of the identification of contaminated and faulty devices. In the broader literature, there is support for the reuse of some devices such as electro-physiology catheters under strict cleaning and sterilisation protocols. Adverse events related to the reuse of medical devices have been reported such as iatrogenic Creutzfeldt-Jakob disease (CJD), however there are few reported cases linked to contaminated medical devices. Research continues into CJD infection control as this requires unique disinfection and sterilisation methods given the strong resistance of prion disease to conventional decontamination methods. The only certain way to avoid the risks (though not quantifiable at present) of reprocessed SUDs as being vectors of transmissible prions is to make all medical devices disposable. Improved awareness and changes in clinical practice have helped to minimise transmission risks. The controversy remains regarding hemodialyser reuse practices as this is extensive in countries such as the USA.

The risks associated with reusing SUDs in patients have not been adequately documented because of a lack of data on the incidence of cross-infection and device malfunction. Such events may be underreported due to a lack of surveillance and device tracking methods, and the possibility of legal liability issues.

The literature reviewed is very device-specific and the reliability of the results is limited because of the diversity of SUDs and methods used to evaluate reprocessing and reuse. It is recognised that greater research is required. The implementation of stricter regulatory environments will improve patient safety and monitoring of reuse practices but not necessarily improve cost-effectiveness.

SECTION 2: BACKGROUND

This Tech Brief was requested by Dr Trevor Nisbet, Senior Advisor, Medsafe, Ministry of Health, New Zealand Government. Staff at Medsafe also provided advisory input into this Tech Brief.

The aim of this Tech Brief was to review the evidence for the safety and effectiveness of the reuse of medical devices labeled as single-use devices.

The governments of Australia and New Zealand have agreed to the formation of a joint agency to control therapeutic goods, including medical devices. At present, the Therapeutic Goods Administration (TGA) controls companies in Australia manufacturing and distributing medical devices. Similar controls will be applied to New Zealand companies manufacturing and distributing medical devices when the joint agency is formed. The TGA has distributed a discussion paper on the reuse of devices labelled as single-use and is proposing that all re-manufacturing of single-use devices (SUDs) occur under a quality controlled environment to meet internationally recognised standards and best practice principles. The Ministry of Health (MoH) needs to decide whether to support a similar action in New Zealand to the TGA proposal.

In December 1994, guidelines published by the MoH in *Prescriber Update*¹ stated that users should always follow the manufacturer's recommendation on reuse of devices unless there was documented evidence to support a deviation. There should be written policy or guidelines for such deviations and documentation to cover all aspects of safety and performance of the device. A recent Controller and Auditor General report dated June 2003 on Management of Hospital Infection Control under Recommendation 29 states that "The Ministry should consider establishing a working party to review information on overseas practices and developments on the reuse of items intended for single-use, with a view to providing timely guidance to DHBs"². This report also contained the results of a survey of what policies and procedures were in place. This showed that all hospitals surveyed had procedures in place covering the reuse of SUDs. These procedures included the existence of hospital reuse committees specially convened for the purpose of assessing which SUDs can be reprocessed and reused. However, the survey also showed that hospitals had only limited auditing of compliance to policies and procedures for the reuse of SUDs.

Currently, hospitals in New Zealand follow the standard **AS/NZS 4187:2003** (a joint Australian and New Zealand standard) on re-usable medical device and surgical equipment cleaning, disinfecting and sterilisation. This standard does not apply to SUDs³. The infection control standard **NZS 8142:2000 Section 4** states that "single use items are manufactured for single patient or single episode. Reprocessing may present a risk to the consumer. Reprocessing is at the Organisation's risk". However, the Controller and Auditor General report states that should there be any reprocessing of SUDs, careful control of any reprocessing in this context should include a precise designation of what devices are SUDs, formal procedures for the approval of SUDs to be reprocessed for reuse, trained and skilled staff to set reprocessing standards for reuse and to check compliance with these standards, and regular audits to ensure that any reprocessing for reuse is carried out according to the manufacturer's specifications, which is somewhat ambiguous because if a manufacturer states that a device is for single use only, directions are not given on how to reprocess it⁴.

¹ New Zealand Ministry of Health (1994). *Prescriber Update*. December 1994, page 18.

² Report of the Controller and Auditor general (2003). *Management of hospital-acquired infection*. Volume Two of Two. Wellington. Available from:

http://www.oag.govt.nz/HomePageFolders/Publications/HAI/HAI_Report_Vol_2.pdf Accessed on 16.03.04.

³ *Ibid* page 135.

⁴ *Ibid* page 135.

This Tech Brief updates the Ministry of Health on the way in which other authorities are controlling the reuse of medical devices labelled as single-use and also provides evidence on the safety and effectiveness of such practices from the published literature. The review provides information for deciding whether or not to implement a similar policy to Australia or whether an alternative policy should be considered.

The literature review of key material on the reuse of medical devices labelled as single-use focuses on a review of the latest practices and developments of overseas health authorities. It also reviews evidence for the safety and effectiveness of the reuse of medical devices labelled as single-use, as presented in the published literature with an emphasis on adverse events linked to single use devices reused on multiple patients.

This Tech Brief on the reuse of single-use medical devices is divided into four sections:

- the first section contains a summary overview
- the second section contains background information
- the third section provides a descriptive outline of the key points of any published protocols, guidelines, actions, recommendations or proposals undertaken by specified health authorities on the reuse of single-use medical devices
- the fourth section is an overview of original primary and secondary research work addressing the safety and effectiveness of reuse devices labelled as single-use.

This review by NZHTA did not include additional aspects of the project such as a review of DHB action on reusing medical devices labelled as single-use devices; a review of the cost for hospitals in New Zealand implementing a policy that does not allow for any reuse of single-use medical devices, including the potential liability of not implementing such a policy; and finally a review of the potential costs associated with implementing a reuse of single-use medical device policy based on the proposed policy under consideration by the Australian Therapeutic Goods Administration (TGA).

SECTION 3: REVIEW OF HEALTH AUTHORITY GUIDELINES AND POLICIES ON THE REUSE OF SINGLE-USE MEDICAL DEVICES

The invaluable role of single-use devices (SUDs) in ensuring sterility and preventing cross-infection is well known. However, while there may be benefit from labelling medical devices “single use only” there are well documented economic costs as well as additional hidden costs such as storage space (larger inventories of SUDs are often required), waste disposal and pollution (Stewart, 1997). The growing popularity for reprocessing and reuse of SUDs has arisen from the perceived economic and environmental benefits and has led to the development of formal reuse policies (Favero, 2001). These policies have been determined primarily by economic considerations and the potential cost savings but also the relative lack of scientific data on the safety (benefits/harms) of SUD reprocessing and reuse practices.

The literature does provide evidence that some SUDs can be safely reprocessed using stringent guidelines while it also provides evidence that others cannot. Documented quality control audits have shown that cleaning, sterilising, and integrity testing standards for reprocessed SUDs can be met in some cases. However, the literature provides little evidence to suggest increased patient risk of an adverse event with medical device reprocessing and reuse because of the inherent difficulties in adequately determining a causal link between the two. Only anecdotal reports are available on the risks of patient injury from device reprocessing techniques, device malfunction, and the transmission of infectious disease from one patient to another through improper cleaning, disinfection and sterilisation. The literature often forms more of a theoretical basis of these concerns than any firm scientific evidence⁵.

There are incomplete data and inadequate monitoring mechanisms to track reprocessed SUDs at many healthcare institutions. Patient adverse events directly related to the reuse of SUDs are often under-reported due to the difficulties in determining the actual causes of such events, the potential liability issues of such events and the inadequacy of reporting systems⁶. There is a lack of uniform standards for the reprocessing of SUDs as manufacturers generally do not provide details on how to do this nor how many times a device may be safely reprocessed. This information is supplied with multiple-use products.

Despite the similarities between SUDs and multiple use devices and the belief that they are inherently the same and are reprocessed in the same way there are in many cases, significant differences in both design and manufacturing materials. Any reuse of a device designed for single-use only may compromise device performance and material properties thereby risking device failure and/or patient injury. More complex devices require disassembly for reprocessing then re-assembly. Sterilisation can damage components or materials the device is made of, and there is a lack of uniform reprocessing standards. Consequently, there has been a move from reprocessing in hospitals to specialised third-party reprocessing but this is also due to the increasing complexity of medical devices because of technology advancement (Dunn, 2002a).

Reprocessing and reuse of SUDs is believed to occur at a large number of healthcare institutions worldwide and a very large number of patients are exposed to reprocessed single-use medical devices. Reprocessing and reuse is particularly common in developing countries due to shortages of medical supplies and limited financial resources (Qian & Castaneda, 2002). Internationally there is a wide diversity in the level of government participation in establishing policies on reuse. The potential public health hazard over the risks of infection and device malfunction is the main reason why such policies are introduced.

⁵ Furman, P. J. (2002). The reprocessing of medical devices labelled for "single use" in the US: an historical overview. Business Briefing: Medical Device Manufacturing & Technology, June, 2000. Available from: <http://www.bbriefings.com/download.cfm?fileID=1964> Accessed on 19.03.04.

⁶ United States General Accounting Office (2000). Single-use medical devices: little available evidence of harm from reuse, but oversight warranted. Available from: <http://www.gao.gov/archive/2000/he00123.pdf> Accessed on 16.03.04.

The review of health authority policies on the reuse of SUDs outlines the latest information available. Overall policy statements tend to be conservative and cautionary with advocacy for more research on the safety and effectiveness of reprocessing and reuse of SUDs, greater quality control mechanisms and more written protocols and guidelines for facilities involved in reprocessing and reuse. The FDA in the United States has the most stringent regulations regarding reprocessing and reuse whereas the EU has no uniform policy governing the reprocessing and reuse of SUDs. The Australian TGA position, like that of the FDA, is for SUD reprocessing to the same standard as the original manufacture, but these regulations are yet to be implemented. In Canada, there are no Federal or Provincial regulations governing the reuse of SUDs. With the FDA regulations now in place, these have set a precedent and allow for strictly regulated reprocessing of SUDs and reuse.

The Australian Therapeutic Goods Administration (TGA)

Reuse of SUDs was found to be very common in hospitals across Australia (Collignon et al. 1996) but has been decreasing since 1994 according to the latest study (Collignon et al. 2003). The most common SUDs to be reprocessed are diathermy pencils and electrophysiology cardiac catheters. The past policy regarding the reuse of medical devices labelled as single-use has tended to be cautious but also somewhat ambiguous. On the one hand, advising against the practice but on the other giving health-care institutions the responsibility of whether or not they approved reprocessing and reuse of single-use medical devices. The 1997 NH&MRC report on the reuse of medical devices labelled as single-use noted that Health Departments in all States and Territories, except South Australia provided policy statements in respect of the reuse of SUDs. Five States and one Territory strongly opposed reprocessing and reuse of devices, despite its widespread practice⁷.

A statement by the TGA dated 21 July 2003 outlined both the current and proposed changes to policy related to the re-sterilisation and reuse of SUDs. The TGA as the national regulator of medical devices would permit the reuse of SUDs but only where the device has been reprocessed to a standard where the devices are as safe as and perform as they would have, when originally manufactured. The TGA standard is that "...the sterilised SUDs must be of the same quality, performance and safety as if it was a new device"⁸.

In July 2001, the Australian Health Ministers Advisory Council (AHMAC) with National Health and Medical Research Council (NH&MRC) advisory, agreed that all reprocessing of SUDs for reuse should be considered a manufacturing activity requiring TGA regulation to the same standards as for the original manufacturer. Reprocessors must demonstrate adequate validation and documentation of procedures that SUD medical devices are safety tested prior to reuse. They need to be licensed by the TGA and comply with rigorous quality manufacturing standards. The new regulatory framework sets the standard so that all reprocessors of SUDs are working within the same regulatory framework.

In May 2002, the National Coordinating Committee on Therapeutic Goods (NCCTG), a sub-committee of AHMAC proposed the following components for regulating reprocessors of SUDs⁹:

- *Quality system auditing and certification of reprocessing facilities.* Any facility engaged in reprocessing will be inspected and licensed on a level equivalent to the original equipment manufacturer (OEM) requirements.
- *Labeling and packaging.* As for original devices and a tracking identification on label.

⁷ National Health and Medical Research Council (1997). Report of the NHMRC expert panel on re-use of medical devices labelled as single use. Available from <http://www.nhmrc.gov.au/publications/pdf/ic8.pdf> Accessed on 10.10.03.

⁸ Department of Health and Ageing, Therapeutic Goods Administration (2003). Statement by the TGA on Regulations for Sterilisation of Single Use Devices, 21st July 2003. Available at <http://www.health.gov.au/tga/docs/html/mediare/mrdevsud.htm> Accessed on 10.10.03.

⁹ Department of Health and Ageing, Therapeutic Goods Administration (2003). Consultation on the regulation of the re-manufacture of single use devices for reuse. Available from <http://www.health.gov.au/tga/docs/pdf/devreuse.pdf> Accessed on 10.10.03.

- *Device tracking.* A mechanism for tracking device usage and location, labeling with a unique identification.
- *Incident reporting, recalls, hazard/safety alerts.* Manufacturers to maintain records of adverse events associated with device use. Report to TGA serious event within 48 hours after event.
- *Technical file or design dossier assessment.* All devices to comply with minimum requirements for safety and performance. Information required for assessment is that required of the original device manufacturer demonstrating conformity with safety and performance requirements. A reprocessor may be able to claim equivalence.
- *Manufacturer's database.* TGA to maintain manufacturer's database on re-manufactured SUDs with detail on device model/classes.
- *Patient consent.* Patients to be adequately advised on possible use of reprocessed SUDs during their procedure to make informed decision to accept a reused medical device and provision made by institution for refusal.

Consultation with the Australian States and Territories took place to discuss this framework. Information seminars followed this to explain the new regulatory framework including requirements and processes for facilities considering the reprocessing of SUDs. These new regulations for the reprocessing of SUDs for reuse were expected to be fully phased in by late 2005.

Some States and Territories have reprocessing facilities that undertake sterilisation of SUDs, however it is in public hospitals where a significant amount of reprocessing of SUDs occurs. These concerns were taken up directly with the States and Territories and an agreement has been reached on the implementation of a national regulatory framework for any re-manufacture of SUDs¹⁰.

In October 2003, the National Coordinating Committee on Therapeutic Goods (NCCTG), reached an agreement on the implementation of a national regulatory framework for re-manufacturing single use devices. This began on 1 December 2003 and has a two-year transitional period. The new system specifies that any facility re-manufacturing SUDs has until December 2005 to comply with the requirements of the *Therapeutic Goods Act 1989* amended by the *Therapeutic Goods Amendment (Medical Devices) Bill 2002* and the *Therapeutic Goods (Medical Devices) Regulations 2002*. A guidance document on the new regulatory system for medical devices in Australia that commenced on 4 October 2002 is available¹¹.

The essential principles for medical devices are divided into two types: general principles which are applicable to all medical devices; and 'particular principles' which are applicable to some medical devices. These principles set out requirements relating to the safety and performance characteristics of medical devices¹². When an SUD is re-manufactured for reuse a device's purpose, design and specifications change from single use to reusable. The person(s) responsible for undertaking this activity is considered a manufacturer and is required to comply with therapeutic goods legislation relating to the manufacture of medical devices¹³. The new regulations on the re-manufacture of SUDs includes all medical devices labelled as single use or single patient use irrespective of the level of risk associated with its use but does not include those SUDs that are opened but unused or did not come into contact with blood, tissue or body fluids¹⁴. The options now available to health care professionals

¹⁰ Department of Health and Ageing, Therapeutic Goods Administration (2003). TGA News Issue 42 (November 2003) - Medical devices. Available at <http://www.tga.health.gov.au/docs/html/tganews/news42/dev.htm#single> accessed on 15.03.04.

¹¹ Department of Health and Ageing, Therapeutic Goods Administration (2003). Australian medical devices guidance document number 22: the essential principles for medical devices. Available at <http://www.health.gov.au/tga/docs/pdf/devguid22.pdf> Accessed on 15.03.04.

¹² *Ibid.*

¹³ Department of Health and Ageing, Therapeutic Goods Administration (2004). FAQ on regulation of the re-manufacture of single use medical devices (SUDs). Available at <http://www.tga.health.gov.au/devices/sudfaq.htm> Accessed on 15.06.04.

¹⁴ *Ibid.*

and health care facilities wishing to reuse SUDs are either to become a manufacturer, find a manufacturer to undertake the re-manufacture of the SUDs or implement a single use only policy¹⁵.

On 10 December 2003, Australia and New Zealand signed a treaty to regulate medicines and therapeutic products in the form of a joint (bi-national) agency replacing the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) to provide a joint regulatory scheme for medical devices as well as medicines. The new single agency will be accountable to both the Australian and New Zealand Governments and is expected to commence operation in 2005¹⁶.

US Food and Drug Administration (FDA)

The FDA website provides documentation on the FDA's reuse of SUDs policy <http://www.fda.gov/cdrh/reuse/index.html>. This has a range of documents with notices, guidance, articles, brochures and also a section on frequently asked questions (FAQs), events, issues and contact information.

Over time, there had been growing reuse of SUDs in the USA. The determination of whether or not a device is "for single use only" is made by the manufacturer, not the FDA¹⁷. However, there was a lack of clear evidence that adverse events were occurring due to reprocessing and reuse of SUDs. Data from the FDA's Medical Device reporting systems indicate that there are few reports of adverse events associated with the reuse of SUDs compared with those reported for new devices. These trends and a lack of data became a concern to the FDA, as not enough information was available to protect the public through insuring that the practice of reprocessing and reusing single-use devices was safe, effective and based on a sound scientific basis¹⁸.

The FDA in 1999 re-examined its policy on the reuse of medical devices labelled as single-use. The FDA had been actively involved with reuse issues over a long period. This included research, inspections, outreach, and compliance investigations. After a number of national meetings and public forums with invited feedback, the FDA produced guidelines on the reuse of SUDs. The underlying principle was an equity approach where original medical device manufacturers (OEMs), third party reproducers and hospitals are now all subject to similar regulatory control. Pre-market requirements applied to OEMs were extended to third-party reproducers, and hospitals for the first time were subject to agency regulatory requirements¹⁹.

The FDA issued a final guidance document in August 2000 entitled *Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*. This required hospitals and third-party reproducers to follow the same regulations as for original manufacturers²⁰. FDA enforcement of these regulations is the same as for original medical device manufacturers. However, non-hospital healthcare entities (physician clinics, outpatient clinics, and non-acute health care facilities – e.g., nursing homes) were not covered, although provision was made to extend this policy at a later date. The guidance did not apply to open but-unused SUDs, permanently implantable pacemakers and hemodialysers (governed by separate guidance).

¹⁵ *Ibid.*

¹⁶ Department of Health and Ageing, Therapeutic Goods Administration (2003). Australia and New Zealand sign treaty to regulate medicines and therapeutic products. Joint press release. Available at: <http://www.health.gov.au/mediarel/yr2003/tw/tw03047.htm> Accessed on 15.03.04.

¹⁷ Healthcare purchasing news. April 2002. The onerous impact of FDA reprocessing. Available from: http://articles.findarticles.com/p/articles/mi_m0BPC/is_4_26/ai_84902764. Accessed on 14.06.04.

¹⁸ US Food and Drug Administration (2002). Reuse of single-use devices. Available at <http://www.fda.gov/cdrh/reuse/reuse-issues.html> Accessed on 16.03.04.

¹⁹ US Food and Drug Administration (1999). FDA's proposed strategy on reuse of single-use devices. Available at: <http://www.fda.gov/cdrh/reuse/singleuse.html> Accessed on 16.03.04.

²⁰ US Food and Drug Administration (2000). Guidance for industry and for FDA staff enforcement priorities for single-use devices reprocessed by third parties and hospitals. Available from <http://www.fda.gov/cdrh/reuse/1168.html> Accessed on 16.03.04.

The guidance document and similar others produced by associated organisations²¹ covered the following areas:

- requirements for pre-market notification and approval of reuse SUDs for non-exempt Class I, II and III devices
- registration and listing of reprocessor facilities and lists of devices reprocessed
- submission of adverse events reports (patient injuries)
- manufacturing, packaging and labeling standards
- tracking of medical devices
- removal or alteration from the market of unsafe devices.

The FDA relied upon an existing medical device classification system (Classes I, II, III) based upon the FDA perceived patient risk as opposed to an earlier scheme called the Review Prioritization Scheme (RPS). Class I devices are considered to pose the least risk to patients and their use not considered to be significant in terms of preventing impairment of health. Class II medical devices are considered to present a greater risk to patients than Class I, but are not life sustaining devices. Class III devices are high-risk products for supporting or sustaining human life (Smith et al. 2002).

Entities were required to register with the FDA and submit a list of devices to be reprocessed (or manufactured) and distributed for use. There are two types of pre-market submissions for medical devices for third-party reproducers and hospitals. One requiring a pre-market notification, a 510(k) clearance process showing that a reprocessed device is mostly equivalent (“substantially equivalent”), in terms of safety and effectiveness to a non-processed SUD. This is required for all non-exempted class I and II devices. The other pre-market medical device approval (PMA) requires valid scientific and clinical evidence on its safety and effectiveness as well as hospitals and third-party reproducers having pre-approval inspection of the site where the medical device will be reprocessed. This is required for all class III devices. The FDA significantly expanded its list of frequently reprocessed SUDs to over 200 devices. Non-listed reprocessed SUDs are subject to the enforcement periods that apply to the class of the device.

Guidance and enforcement of pre-market requirements for hospitals and third-party reproducers was to be phased in over 2001 and 2002, a longer time frame given the large diversity of SUDs, and limited FDA resources. This was also to prevent shortages of devices and to enable organisations time to gain familiarity with FDA regulations. The FDA intended to enforce pre-market submission requests (510K, PMA non-exempt) during this period, however there were delays and extensions during the phase in of pre-market approvals for some reprocessed SUDs²². In October 2002, the FDA amended the Federal Food, Drug and Cosmetic Act by adding section 510(o) providing new regulatory requirements for SUDs. This provision was included to ensure that reprocessed SUDs for 510(k)s are substantially equivalent to predicate devices. The new provisions require that 510(k)s for certain reprocessed devices identified by the FDA must include validation data, such as cleaning and sterilisation data, and functional performance data to demonstrate that device integrity remains substantially equivalent to its predicate device after a maximum number of times of reuse. Some previously exempt reprocessed SUDs became no longer exempt from pre-market notification requirements and submitted 510(k)s are now required to have validation data²³.

During the implementation process there were postponements in the enforcement of manufacturing requirements for hospitals. Concerns were raised over the ability to enforce the new requirements in

²¹ Association of periOperative Registered Nurses (AORN) (2001). AORN guidance statement: reuse of single-use devices: AORN. Available from <http://www.aorn.org/about/positions/pdf/Reuse.pdf> Accessed on 19.03.04.

²² US Food and Drug Administration (2001). FDA actions on reprocessed single use devices. Available from: <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01098.html> Accessed on 16.03.04.

²³ US Food and Drug Administration (2003). Federal Register, Notices, volume 68, number 83, pages 23139-23148. Available from <http://www.fda.gov/OHRMS/DOCKETS/98fr/03-10413.html> Accessed on 15.06.04.

hospitals doing reprocessing, because of the requirements that the hospital should be similar to a manufacturer and inadequate resources to cover so many additional sites²⁴.

The FDA has enlisted some additional assistance from organisations such as Joint Commission on the Accreditation of Healthcare Organisations (JCAHO) and Centers for Medicare and Medicaid Services (Dunn, 2002a). This has been limited to providing information to institutions on the FDA policy and auditing the reuse of SUDs.

The United States General Accounting Office GAO had earlier acknowledged difficulties with hospitals understanding and complying with the new requirements²⁵. The FDA guidance is unclear as to what control standards will be used – i.e., the original equipment manufacturers' FDA data files as a control to compare reprocessed medical devices for substantiating equivalence (Smith et al. 2001). There will be different standards for meeting PMAs – i.e., clinical trials. It is not clear whether the FDA will accept pre-market notifications by applicants for groups of similar items rather than for each model. Devices may be a different models but all function similarly – e.g., laparoscopic trocars which vary in size, sharpness and thread (Dunn, 2002a).

There is a perception that the new FDA policy will increase the cost of devices reprocessed at hospitals and third party operations through a drop off in demand for reprocessed SUDs and a rise in demand for new SUDs with resulting price rises from manufacturers. This may also lead to reprocessors going out of business although third party reprocessors are more likely to be able to adapt to the new FDA regulations than hospitals because they will have already collected data required by the FDA (Dunn, 2002a). The FDA intends to take enforcement action against hospitals and third party reprocessors that do not adequately complete submissions for pre-market approval or in situations where a reprocessed and reused medical device causes harm. The penalties range from a public health alert release, FDA warning letter, and if the regulatory violation is not satisfactorily rectified, a mandatory recall, injunction of the facility, and fine and prosecution.

The new reprocessing standards are difficult to meet, particularly for hospitals and there are indications that reprocessing in these settings has declined significantly. Hospitals do not have the expertise to comply with the new regulations and to do so it would be best to rely on the dozen or so reprocessors for the service. The FDA provides alternatives to allow reprocessing under strict controls, but ultimately hospitals have to decide which method they follow and the economics of the different alternatives. Safety and effectiveness considerations are of primary importance in FDA policy. The new policy brings about equality between hospital and third party reprocessors and facilitates the tracking of devices and adverse events. However, these benefits are undermined by the incomplete application of the policy in non-hospital healthcare which remains essentially unregulated.

Health Canada

In Canada, there are no Federal or Provincial regulations governing the reuse of single-use medical devices. Currently, Health Canada does not regulate the reuse of medical devices by health care facilities or reprocessing of these devices by third-party reprocessors. The use or reuse of medical devices falls outside the governance of the Food and Drugs Act and the Medical Devices regulations. These acts have authority over the manufacture and sale of medical devices and were never intended as regulations over the use (including reuse) of such medical devices.

There are no established standards for safe sterilisation practices in hospitals for any device. At the Ontario Hospital Association conference on reuse held in Toronto on 26 March 2003, Dr Robert Peterson, Director General of Health Canada's Therapeutic Products Directorate, announced that Health Canada intended to address the issue of reprocessing if there was lack of follow-up action by other organisations. Health Canada could establish regulations similar to those of the FDA that assert jurisdiction over reprocessing of medical devices²⁶.

²⁴ US Food and Drug Administration (2001). Changes in enforcement of FDA's requirements on reprocessing of single-use devices. Available from <http://www.fda.gov/cdrh/reuse/reuse-letter-092501.html> Accessed on 16.03.04.

²⁵ United States General Accounting Office (2000). Single-use medical devices: little available evidence of harm from reuse, but oversight warranted. Available from <http://www.gao.gov/archive/2000/he00123.pdf> Accessed on 16.03.04.

²⁶ Neufeld, P.N. Medical Devices Bureau, Health Canada. Personal communication 30/9/03.

In two Provinces, directives have been issued to their hospitals regarding the practice of reuse. The Conseil d'Évaluation des Technologies de la Santé du Québec (CETS) in 1996 issued a statement recommending that single-use cardiac catheters should not be reused because of the possibility that Creutzfeldt-Jakob Disease (CJD) might be transmissible through blood. In 1997, this recommendation was amended to say that single-use catheters should not be reused if they had come in contact with patients considered to pose a risk of being a vector for CJD. However, if the previous patient was not considered to be in this category, reuse did not pose an unacceptable risk²⁷. Manitoba, in 1999 prohibited (a ban still in force) the reuse of "critical contact" SUDs. These are devices that contact blood or a sterile body cavity. It is expected that the Ontario Hospital Association will recommend that Ontario hospitals not reuse critical and semi-critical SUDs and will recommend the reuse of other SUDs only if Health Canada regulates such practice.

A Communicable Disease Report in December 2001 outlined the results of a survey of medical device reuse in health care facilities (acute-care hospitals)²⁸. This had a 57 percent response rate out of 741 hospitals surveyed. The survey results showed variable reuse policies across the Provinces and Territories, especially with regards to hospitals having reuse committees. The survey found the reuse of SUDs to be widespread, a lack of reuse committees in hospitals and a lack of written reuse protocols for many items. There had been a substantial increase in reuse since the last survey in 1986 and the existence of protocols had diminished.

The CHA (Canadian Healthcare Association) compiled a report in 1996 on reuse of SUD guidelines for Healthcare facilities across Canada²⁹. This found formal position statements on reuse relatively rare and divergent across organisations. These included the Canadian Council on Health Services Accreditation (CCHSA) which had no formal standards on reuse, the Canadian Medical Device Industry Trade Association which had a stated formal position against reuse of medical devices, while the Community and Hospital Infection Control Association Canada, Canadian Nurses Association, the Canadian Medical Association and others had no position statements on reuse. Canadian standards organisations which deal with national standards on cleaning and sterilisation were found to have very limited reference to reuse, with most standards not applying to reuse, and interested hospitals referred to Health Canada, and recommending reuse only where the manufacturer specifically recommended it.

The CHA recommended that guidelines should be regularly reviewed and updated and include recommendations that a reuse program include economic analysis, reprocessing procedures and validation of these, quality assurance, development of an employee training programme, and must be regularly reviewed and updated. The interdepartmental reuse committee should lead development of the reuse programme with multi-faceted involvement from specialties such as epidemiology, infection control, biomedical engineering, ethics etc. The report also recommended that reuse should not be on an ad hoc or casual basis but reuse should be considered on a case by case basis taking into account the uniqueness of each device with its own specific design, construction, materials, cost, intended use and cleaning procedure. The guidelines do not strongly advocate a position for or against reuse of SUDs but provide the basis of a framework by which healthcare facilities can assess the benefits and safety of reprocessing/reuse of SUDs.

The reuse of implants was considered separately in guidelines. Removal of the implant from the patient usually occurs after death and requires prior patient consent, and consent prior to new patient implantation. The safety of the reuse of pacemakers is documented in literature and the practice is undertaken in many countries. The safety issues here revolve around improper selection, cleaning, testing and sterilising. Refurbishing of these devices can be hospital-based, though there is one manufacturer in Canada.

Legislation (Canada's Food and Drugs Act and Medical Devices Regulations) exists for the manufacture and sale of medical devices but this does not apply to the use of medical devices in

²⁷ *Ibid.*

²⁸ Health Canada (2001). Reuse of single-use medical devices in Canadian acute-care healthcare facilities, 2001. Canada Communicable Disease Report volume 27, number 23. Available from <http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/01pdf/cdr2723.pdf> Accessed on 16.03.04.

²⁹ Canadian Healthcare Association (1996). The reuse of single-use medical devices - guidelines for healthcare facilities. Available from <http://sprojects.mmi.mcgill.ca/heart/carechain.html> Accessed on 18.03.04.

hospitals. Regulation does apply to those that reprocess and reuse implantable devices that are classified as having been sold if implanted permanently in a patient (CHA, 1996).

European Union

There are three Medical Device Directives currently in place, the Directive of Active Implantable Medical Devices (90/385/EEC), the Medical Devices Directive (93/42/EEC), and the Directive of In Vitro Diagnostic Medical Devices (98/79/ec). These directives relate to quality assurance issues and the three Medical Device Directives include provisions (harmonised standards legislation) for mandatory CE Marking of all products covered by them and are applicable to all medical devices placed on the EC market³⁰. The 93/42/EEC relates to medical device definition, full quality assurance, production quality assurance and product quality assurance for the manufacture and marketing of medical devices. Under these directives, a competent authority is to be nominated in each EU member country to ensure compliance with the provisions of the Medical Device Directives. These authorities are to ensure that Notified Bodies are designated to carry out conformity assessment procedures, that adverse incidents are reported, that unsafe devices are withdrawn from the market, the handling of applications for clinical investigation, the enabling of the Directives to be passed into law through statutory instruments and that only devices with the CE marking (CE mark) are permitted onto the market³¹.

The Medical Devices Directive 93/42/EEC ensures free trade within the EEC and provides safety harmonisation standards for patients and users and regulation for post market activities under the responsibility of national authorities. The MDD 93/42/EEC directive does not regulate the reprocessing and reuse of SUDs. The practice of reprocessing and reuse of SUDs is widespread throughout EU member countries. Neither the EU or member states appear to adequately address the issue of reuse.

Eucomed (The European Association of Medical Device Suppliers) is an umbrella organisation for individual companies and trade associations active in the medical technologies field in Europe. It represents the medical technologies industry in Europe and raises the awareness of issues of importance for the industry. It has called on European governments to properly regulate, enforce and monitor existing European and national policies and legislation on the reprocessing of single-use medical devices by reprocessors, hospitals, original manufacturers and medical practitioners. It has called on governments to act in order to protect the health and safety of patients and workers^{32 33}. It believes there are significant risks for patients and healthcare workers from the reuse of SUDs. Specifically, these are the risks of cross infection and device failure. The risk of cross-infection includes the transmission of Creutzfeldt-Jakob Disease (CJD) by silver electrodes used for recording activity of the brain and by neurosurgical instruments, and the risk of hepatitis B and C infection, spread by contact with the blood of the infected person on a contaminated reused instrument or through blood transfusion. There can also be a risk of device impairment from the effects of reprocessing³⁴.

An overview of EU member States is shown in **Table 1 (overleaf)** on the current legal status of refurbishing single-use products in individual member countries (Source Eucomed press release, Issue 03/03)³⁵.

³⁰ Wellkang® Group (1999-2004). Brief Introduction of EU Council Directive 93/42/EEC Medical Devices. Available from: <http://www.ce-marking.org/directive-9342eec-medical-devices.html> Accessed on 15/10/03.

³¹ *Ibid.*

³² Eucomed (undated). Resolution – call for EU action. Brussels, Eucomed. Available from: <http://www.eucomed.be/?x=4&y=46&z=125&id=442> Accessed on 15.10.03.

³³ Eucomed (2002). Manifesto: Resolution by European Associations calling on EU action to regulate the reprocessing of single use medical devices in order to protect the health and safety of patients and healthcare workers. Brussels, Eucomed. Available from <http://www.eucomed.be/docs/Final%20Revised%20Manifesto%20December%2020%20with%20logo.pdf> Accessed on 15.10.03.

³⁴ Eucomed (2002). Patients in danger: the reuse of single-use medical devices in Europe. Brussels, Eucomed. Available from: <http://www.eucomed.be/docs/final%20briefing%20paper%20June2002.pdf> Accessed on 15.10.03.

³⁵ Eucomed (2003). Manifesto calling for EU regulation of all reprocessing of single use medical devices: final adoption by Eucomed and five stakeholders in healthcare. Press release issue 03/03. Brussels, Eucomed. Available from accessed on <http://www.eucomed.be/docs/Press%20release%2003.03%20Reuse%20manifesto.pdf> Accessed on 15.10.03.

Table 1. EU Country Status of Regulatory Control for the Refurbishment of Single Use Products

Country	Level of Regulation	Description
Austria	None	Austrian Competent Authority recommends no reuse. Federal Ministry of Health preparing an ordinance on refurbishing in/for healthcare providers.
Belgium	None	
Denmark	None	Refurbishment permitted, responsibility of users. No special market surveillance or legal reference.
Germany	Regulation on reprocessing (registration of reprocessing activity only) but no distinction between single and multiple use devices.	<p>The ordinance on operating medical devices used as sterile or aseptic devices requires validated reprocessing, this considered to be adequate if official reprocessing recommendations followed (based on device risk and reprocessing requirements levels). This prohibits reuse against a device's intended use, so reuse in this context is illegal. Regulation does not clarify if reuse of SUD is legal and varied legal opinions on subject of compliance with German law or not.</p> <p>In certain cases no reprocessing should take place. For some "critical device" reprocessing, it is not mandatory to follow ISO guidelines.</p> <p>The MDD 93/42/EEC applies where reprocessors that provide to third parties devices to be used sterile or aseptically are to be supervised by a Competent Authority.</p>
Greece	None	
Finland	Ban	Regulations on medical devices state that a medical device must be used in accordance with its intended purpose as specified by the manufacturer and that users must follow these instructions and ensure functional reliability of devices and report adverse incidents.
France	Ban	The Health Authority has advised against the reuse of SUDs since 1984 and upheld this through court actions in 1999 and 2000. Refurbishing of SUDs seen as misleading the public as patients are taking a greater risk and not deriving any extra advantage and that the product is invoiced as new when it is in fact reused. In June 2001, law against reuse of SUDs published.
United Kingdom	The Health Authority advise against the reuse of SUDs	The Medical Devices Agency request not to reuse SUDs.
Hungary	Ban	The Official Sterilisation Guideline advises that single use items should not be resterilised or reused because of possible changes in device material and defects from the resterilisation process. The National Health Scientific Committee issued a statement against the resterilisation of SUDs.
Italy	Ban, case interpretation	Case interpretation by Health Authority.
Norway	Partial regulation (not clear)	Unclear degree of implementation and no registration of device reprocessing. A reprocessed device is defined as a product produced in a hospital that must meet full safety requirements subject to Health Authority interpretation.
Portugal	Ban, case interpretation	The Health Authority position is that refurbishing compromises the health and safety of patients and users beyond acceptable limits. It cannot be proved that the requirements of the MDD 93/42/EEC directive can be maintained.
Sweden	Partial regulation	Refurbished SUDs have to meet the basic requirements of the MDD 93./42/EEC and their use requires patient informed consent.
Switzerland	None	
Spain	Any reuse of SUDs that endangers a patient is illegal.	The law states that medical devices must be used according to the manufacturers intended use for the product.

Source: Eucomed 2003

From **Table 1** above, Finland, France, Germany, Italy, UK, Portugal, Spain and Sweden have all introduced various degrees of regulation (including a total ban) on refurbishing and reuse of SUDs. Despite this, the practice remains widespread in EU countries. No European regulatory authority has a documented policy supporting the reuse of SUDs and no rigidly enforced regulation to allow safe reuse. While not officially encouraging reprocessing and reuse, some individual EU countries by default have no regulatory guidelines for reprocessing and reuse which indirectly condones the practice. Loopholes in the law or non-enforcement also allow for uncontrolled reuse. The arguments commonly are that ‘single use’ is defined as not being a part of the intended use and regulations can be got around by not having to place these devices on the market again as for new devices through in-house or contract refurbishing³⁶.

United Kingdom Medicines and Healthcare products Regulatory Agency

The Medical Devices Agency (MDA) was merged with the Medicines Control Agency (MCA) in April 2003 to form the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA, an Executive Agency of the UK Department of Health, helps safeguard public health through working with users, manufacturers and lawmakers regarding suitable safety, quality and performance standards for medicines and medical devices and compliance with appropriate Directives of the European Union.

The MHRA (formerly MDA) strongly advise against the reuse of SUDs. The position is that “devices designated for ‘single use’ must not be reused under any circumstances” (MDA DB2000 (04) August 2000). In this bulletin, the MDA view is that the reuse of ‘single use’ devices compromises the safety, performance and effectiveness of such devices on patients and exposes both the reprocessor and patient to greater risks than any perceived benefits. The legal implications of the MDA position are that firstly, anyone who reprocesses or reuses a medical device which the manufacturer intend for use only on a single occasion bears the full responsibility for the safety and effectiveness of that device. Secondly, a reprocessor that passes on a reprocessed single use device to a separate legal entity has the same obligations under the Medical Devices Regulations as the original manufacturer of the device.

The MDA argument against reprocessing SUDs is that reprocessing may alter device characteristics so that they no longer meet with the manufacturer’s original specifications and therefore could compromise the device performance. Also, that reprocessing of SUDs requires extensive testing and validation and that few organisations are capable of meeting these stringent demands³⁷. If the manufacturer does not specify device reuse suitability, then it is the responsibility of the user to ensure safety and adequate duty of care to the patient and to staff. The disregard of official information may transfer legal liability for the safe performance of the device from the manufacturer to the user (individual or organisation) that uses them³⁸.

The MDA position reflects the implementation of the European Council Medical Devices Directive MDD 93/42/EEC into UK law in June 1998. It also is based on the Health Service Circulars HSC 1999/178 on Variant Creutzfeldt-Jacob Disease (vCJD) and minimising the risk of transmission: “single use instruments should be discarded after use and never be reprocessed”³⁹.

³⁶ Eucomed (2002). Reuse of single use devices: Eucomed presentation at November 22 EU Health Policy Forum. [Powerpoint presentation]. Brussels, Eucomed. Available from: <http://www.eucomed.be/docs/Reuse%20of%20Single%20Use%20Devices%20%20hpf.pdf> Accessed on 15.10.03.

³⁷ Department of Health: Medical Devices Agency (2000). Medical devices and equipment management: Repair and maintenance provision. MDA DB2000(02) June 2000. Available from [http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/981591cd2aa3466600256a7600410666/b7d0158a173d0c5a80256c8b004de2b7/\\$FILE/db2000\(02\).pdf](http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/981591cd2aa3466600256a7600410666/b7d0158a173d0c5a80256c8b004de2b7/$FILE/db2000(02).pdf) Accessed on 10.10.03.

³⁸ Department of Health: Medical Devices Agency (2000). Single-use medical devices: Implications and consequences of reuse. MDA DB2000(04) August 2000 Available from [http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/981591cd2aa3466600256a7600410666/b7d0158a173d0c5a80256c8b004de2b7/\\$FILE/db2000\(04\).pdf](http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/981591cd2aa3466600256a7600410666/b7d0158a173d0c5a80256c8b004de2b7/$FILE/db2000(04).pdf) Accessed on 10.10.03.

³⁹ Department of Health: NHS (1999). Variant Creutzfeldt-Jacob Disease (vCJD): minimising the risk of transmission. HSC 1999/178. Available from http://www.decontamination.nhsestates.gov.uk/downloads/HSC178_1999.pdf Accessed on 10.10.03.

HSC 1999/179 on assurance in infection control and the decontamination of medical devices states in the section on staff action (iv) “never reuse medical devices designated for single use”⁴⁰. User comments on the first version of the bulletin published in 1995 (MDA DB 9501) which was subsequently replaced by DB 2000(4)⁴¹ have also influenced the MDA position.

Medical Industry Association of New Zealand (MIANZ)

This association represents about 120 companies importing, distributing and manufacturing medical devices in New Zealand. As New Zealand has no pre-market assessment and no registration of medical devices supplied to health providers here, legislation only covers post-market monitoring activities www.mianz.co.nz. The position of the MIANZ on the reuse of SUDs is as follows:

- reuse usually involves reprocessing a device that is designed and labelled for single-use. Such reprocessing creates a new device
- manufacturers have the right to design and label devices as single-use and the MIANZ opposes any regulatory requirement that manufacturers test or label these devices for multiple use
- the MIANZ opposes the reuse or promotion of reuse of devices designed or labelled for single-use.

The MIANZ represents the concerns of manufacturers regarding product quality, safety and liability issues. Manufacturers believe that devices labelled and designed as single-use are single-use only and should not be required to modify their products to accommodate reuse practices. From the MIANZ perspective, the published literature demonstrates adverse events and contamination related to reuse of single-use devices and that all legal and regulatory responsibility on reuse rests with facilities authorising reuse and also parties conducting reprocessing. Manufacturers have no enforcement power in terms of preventing the reuse of SUDs⁴².

⁴⁰ Department of Health: NHS (1999). controls assurance in infection control: Decontamination of Medical Devices. Available from http://www.decontamination.nhsestates.gov.uk/downloads/HSC179_1999.pdf Accessed on 10.10.03.

⁴¹ Department of Health: Medical Devices Agency (1995). The reuse of medical devices supplied for single use only. DB 9501. Available from <http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwMDASafetyWarnings/34DE0FBF319D0FB180256C8B003959DA?OPEN> Accessed on 10.10.03.

⁴² Medical Industry Association of New Zealand (undated). Position paper on the reuse of single-use medical devices. Available from <http://www.mianz.co.nz/PositionPaper2.htm> Accessed on 30.10.03.

SECTION 4: REVIEW OF ORIGINAL PRIMARY AND SECONDARY RESEARCH ON THE SAFETY AND EFFECTIVENESS OF REUSE DEVICES LABELLED AS SINGLE-USE

Study inclusion and exclusion criteria

For the fourth section of the review, inclusion and exclusion criteria were applied to the abstracts captured by the literature searches to identify those to be retrieved as full text. Selection criteria were then applied to these retrieved papers in order to identify the final set of papers eligible for overview and summary in the Evidence Tables.

Peer reviewed studies were considered for this section of the review if they used one of the following study designs:

- systematic review or meta-analysis design
- controlled clinical trials (randomised, quasi-randomised or non-randomised)
- analytic studies (e.g., cohort and case-control design)
- quasi-experimental studies (e.g., before/after design)
- descriptive studies and descriptive analytic studies (e.g., cross-sectional, longitudinal studies, case series design).

Studies of higher quality and levels of evidence (e.g., SRs or RCTs) were used in preference to lower level evidence (e.g., descriptive studies). Levels of evidence are based on the notion that experimental study designs minimize or eliminate bias more effectively than non-experimental designs.

Inclusion criteria

The following criteria will be used to include studies for overview:

- studies examining evidence for the safety and/or effectiveness of reused medical devices manufactured and labeled as single-use used on multiple patients
- studies examining the reuse of medical devices manufactured for and labeled as single-use which have undergone reprocessing either by an institutional health-care provider (e.g., hospital) or a third party reprocessor
- studies with a population of general hospital patients, as inpatients, outpatients, ambulatory, and presenters at emergency departments, patients receiving any form health care in community settings – e.g., GP clinics, dental surgeries, private practice specialties
- studies with a comparator group of patients who received equivalent single-use medical devices that had not been previously opened or used/reprocessed or studies without a comparison group
- studies where primary outcomes considered include one or more of the following:
 - incidence of infection
 - mortality
 - identifiable patient adverse events (e.g., endotoxin reactions from resterilisation)
 - cost-effectiveness.

- secondary outcomes include one or more of the following:
 - device failure
 - device damage
 - non-sterile device
 - unclean device.

Note: Primary outcomes were considered to be those where the reuse of a single-use medical device directly or indirectly causes a patient adverse event. Secondary outcomes are considered to be outcomes measuring the incidence of adverse events related directly to the medical device itself.

- studies written in English and published from January 1997 onwards.

Exclusion criteria

The following criteria were used to exclude studies from overview in **Section 4** of the review:

- studies evaluating medical devices either manufactured and/or labeled as reusable
- studies assessing the safety and/or efficacy of single-use medical devices previously opened but not used
- studies evaluating reused single-use medical devices both unprocessed and reprocessed used on the same patient
- studies evaluating adverse events caused by the first-time use of single-use devices
- studies evaluating reused single-use devices that have not been reprocessed
- studies comparing the safety and/or efficacy of disposable medical devices with reusable medical devices
- studies with inadequate description of methodology and/or results or significant error or methodological problems
- narrative reviews, expert opinion, letters to the editor, comments, editorials, conference proceedings, books and book chapters. This material is covered in part in **Section 3** of the review.

MAIN SEARCH TERMS

Details of the search strategy are presented in **Appendix 2**.

Main search terms

Medline, Cinahl & Cochrane Controlled Trials index terms: disposable equipment equipment reuse.

The above index terms were adapted for use in sources of information without indexing.

Additional free text keywords (used in all sources): reuse\$, reprocess\$, single-use, disposable, SUD, SUDs.

The search was restricted to information from January 1997 onwards in English. Searches were carried out from 9 to 10 September 2003, and updated on 15 to 16 March 2004.

SEARCH SOURCES

The NZHTA CORE Search was employed. Characteristics of the Core search include: essential sources only, major databases and secondary sources, and mostly published and indexed literature. For more detail about the search sources refer to the NZHTA Search Protocol at: <http://nzhta.chmeds.ac.nz/nzhtainfo/protocol.htm> Steps 1-9 (Core sections).

In addition, bibliographies of retrieved papers were scanned for further relevant items, and appropriate websites searched, particularly those of government regulatory bodies and associations of medical manufacturers.

Bibliographic databases

- Medline
- Embase
- Cinahl
- Science Citation Index
- Current Contents
- Cochrane Controlled Trials Register
- Index New Zealand

Review databases

- Cochrane Database of Systematic Reviews
- Health Technology Assessment database
- NHS Economic Evaluation database
- Database of Abstracts of Reviews of Effects
- ACP Journal Club

Government website sources

- Australian Therapeutic Goods Administration <http://www.tga.gov.au>
- US Food and Drug Administration <http://www.fda.gov>
- Health Canada Health Protection <http://www.hc-sc.gc.ca>
- Health Protection <http://www.hc-sc.gc.ca/english/protection>
- Therapeutic Products Directorate http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/aboutus_e.html

- European Parliament – medical devices publications http://europa.eu.int/enterprise/medical_devices/index.htm
- UK Department of Health Medicines & Healthcare products Regulatory Agency – Medical Devices Division <http://www.medical-devices.gov.uk>
- Ministry of Health Singapore <http://app.moh.gov.sg>

Other sources

- World Health Organisation <http://www.who.int>
- Global Harmonization Task Force <http://www.ghhf.org>
- Medical Device Association of New Zealand <http://www.mianz.co.nz>
- Eucomed <http://www.eucomed.org>
- US Association of periOperative Registered Nurses <http://www.aorn.org>
- Canadian Healthcare Association <http://www.cha.ca>
- Medical Industry Association of New Zealand Inc <http://www.mianz.co.nz>

Other websites as located in the course of the search.

OVERVIEW METHODOLOGY

Articles were reviewed using in-house checklists developed by NZHTA for the appraisal of primary and secondary studies. Summaries of results are presented in both text and tabular form, conclusions drawn from the study design and any significant limitations noted.

The evidence presented in the selected research studies will be classified using the dimensions of evidence defined by the National Health and Medical Research Council (NHMRC, 2000). The designations of the levels of evidence are shown in **Table 2** below.

Table 2. Designations of levels of evidence*

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly-designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from descriptive studies – e.g., case series, either post-test or pre-test/post-test designs

*Modified from NHMRC (2000)

The Evidence Tables for research studies appraised in **Section 4** of the Tech Brief will present key information summaries described below:

- **study citation, source and design:** including authors, year published, country of origin, study design and level of evidence
- **medical device and study purpose:** the specific medical device of interest and study aims
- **study methods:** methods used in the conduct of the study
- **outcomes:** study results
- **comments and conclusions:** authors conclusions.

RESULTS OF CRITICAL APPRAISAL

From the above search strategy, 367 potentially relevant articles/abstracts were identified, of which 97 were retrieved in full text. Of these retrieved articles, 36 were included in **Section 3** of the review on health authority guidelines and policies on the reuse of single-use devices and 29 primary research studies were reviewed in **Section 4** (listed in **Appendix 4**). Another 30 retrieved articles were excluded and are presented in **Appendix 3**. These studies were excluded for the following reasons: letters to journals, expert opinion/narrative review, legal/malpractice issues surrounding reuse of SUDs, reusable devices, previously opened but unused medical devices, policy statements, news articles and studies out of the scope for this Tech Brief.

Twenty-nine retrieved articles were appraised. Included papers are presented in each evidence table below in alphabetical order. Most of the studies were graded as level IV evidence with prospective/retrospective case series or before/after study designs. There were also three randomised controlled trials (one grade II and two grade III-2 evidence). Thirteen studies were set in the USA, four in Germany, four in Canada, two in Turkey and one in each of Australia, Hong Kong, Kuwait, the Netherlands, Spain and Sweden. Of the 29 primary research studies, 22 were laboratory research studies with disease-orientated evidence and seven studies involved humans, measuring outcomes of direct importance to patients.

The evidence tables comprise:

Table 3 (pages 20-26) on the safety and effectiveness of single-use device reuse – cardiovascular medical devices.

Table 4 (pages 27-28) on the safety and effectiveness of single-use device reuse – anaesthesia devices.

Table 5 (page 29) on the safety and effectiveness of single-use device reuse – sphincterotome devices.

Table 6 (page 30) on the safety and effectiveness of single-use device reuse – emergency intubation airway devices.

Table 7 (pages 31-34) on the safety and effectiveness of single-use device reuse – disposable plastic trocars.

Table 8 (page 35) on the safety and effectiveness of single-use device reuse – biopsy forceps.

Table 9 (pages 37-38) on the safety and effectiveness of single-use device reuse – orthopaedic fixator components.

Table 3. Evidence table on the safety and effectiveness of single-use device reuse – cardiovascular medical devices – PTCA catheters

Authors, study design, country Evidence grading	Medical Device and study aim	Methods	Results	Conclusions
Brown et al. (2001) Prospective case series (laboratory research) USA Grade IV	Device retrieval and analysis study with the single patient use and simulated reuse of balloon catheters for Percutaneous Transluminal Coronary Angioplasty (PTCA). Device manufacturers not specified.	Used balloon catheters (650, of 30 models from multiple manufacturers) retrieved from medical facility, given low-level disinfection, soaking and flushed clean, visual inspection by US FDA facility and tested for balloon compliance. Some balloons were selected or Ethylene Oxide-sterilisation and a simulated reuse protocol. Device performance properties of new and reused devices were analysed and compared against manufacturers specification.	<ul style="list-style-type: none"> ▪ no standard test for catheter models as the effect of use and EO-sterilisation is model specific ▪ some models of devices became less compliant (trend rather than cumulative effects) over time after repeated simulated reuse and re-sterilisation, though some recovery apparent from reuse compliance testing at high pressure tests show model specific changes to catheter slipperiness after repeated re-sterilisation. 	<ul style="list-style-type: none"> ▪ author's conclusion: there are difficulties generalising about the effects of reprocessing and reuse of the class of PTCA devices as these are model specific.
Browne et al. (1997) Prospective case series USA Grade IV	Used device retrieval and reprocessing analysis of the performance of reused balloon catheters for Percutaneous Transluminal Coronary Angioplasty (PTCA). Manufacturer and model of devices specified in study as Guidant Corporation (Guidant® PE-600® balloons) and Cordis Corporation (Cordis® Duralyn™ Balloons). There were 18 over-the wire, 76 monorail and 30 perfusion balloon catheters used in the study.	Used balloon catheter (by product group) reprocessing with decontamination, cleaning, tests for endotoxins, physical testing, quality assurance, EO-sterilisation and repackaging. Follow-up pilot study to analyze catheter performance through failure rates in new versus reused balloons. 107 patients (mean age 64, 56% male) with coronary insufficiency (69), unstable angina (22), acute MI (16) having PTCA with 122 lesions attempted. These patients were compared with a case-matched control group (n=108) retrospectively from database using new devices for frequency of fever.	<ul style="list-style-type: none"> ▪ safety: no incidents of catheter rupture under rated burst pressure or pyrogen reactions ▪ performance: angiographic failure rate was 7%. Previous studies cited as showing failure rates of ~ 10% ▪ cost effectiveness analysis: estimates of up to 40% savings on original invoice cost of new devices to the hospital. 	<ul style="list-style-type: none"> ▪ author's conclusion: PCTA catheters that are reprocessed under strict controls appear to be safe, effective and cost-effective for reuse.

Table 3. Evidence table on the safety and effectiveness of single-use device reuse – cardiovascular medical devices - PTCA catheters (continued)

Authors, study design, country evidence grading	Medical Device and study aim	Methods	Results	Conclusions
Unverdorben et al. (2003) Prospective case series (laboratory research) Germany Grade IV	Laboratory trial assessing the quality of Percutaneous Transluminal Coronary Angioplasty (PTCA) balloon catheters after up to three resterilisation cycles. Both catheter types were monorail systems, the exact materials of the devices were not disclosed by manufacturers nor were manufacturers identified in the study.	Forty resterilised (cleansed by disinfectant, desalinated, dried by air, packaged and then gas sterilised) PTCA catheters from two different manufacturers (1.5 mm and 3.0 mm diameters) taken from the shelf. Independent research institute tested mechanical properties: burst pressure, nominal diameter, crossing profile, and balloon surface. These were compared these with new catheters.	<ul style="list-style-type: none"> ▪ the crossing profile increased between 22.5%-39.2%, and no additional deterioration after repeated sterilisations ▪ the nominal diameter either increased or decreased by up to 47%, mostly smaller than larger in diameter ▪ the burst pressure remained well above manufacturers values for 1.5mm balloons. For 3.0mm balloons rated value dropped well below in 40-50% of trials ▪ change of parameters could have been attributed to either reuse or re-inflation, not differentiated. 	<ul style="list-style-type: none"> ▪ author's conclusion: there was observed deterioration in the mechanical properties of the two devices tested after re-sterilisation up to three times.
Yang et al. (1997) Prospective case series (laboratory research) Canada Grade IV	Suitability of reuse of single use poly-esterurethane Intra-aortic Balloon (IAB) devices provided by three cardiac surgery facilities. Devices used in study from Datascope Corp. (Paramus NJ, USA) and Aries (Woburn, MA, USA).	112 used devices rinsed in de-ionised water, dried in air, kept at room temperature. Checked through: <ul style="list-style-type: none"> ▪ macroscopic examination ▪ scanning electron microscopy ▪ leakage inspection ▪ mechanical analysis ▪ infrared spectroscopy. <p>Compared with three unused devices as controls.</p>	<ul style="list-style-type: none"> ▪ no IABs failed in initial use ▪ most devices retained their physical and mechanical properties similar to control devices and stable chemistry after short-term in vivo usage ▪ bending flaws on lumens and heavy creases on balloons (from retrieval procedure problem) ▪ widespread contamination with residual organic debris. 	<ul style="list-style-type: none"> ▪ author's conclusion: reusing IAB's will require cleaning but perceived difficulties in removing residual debris and high risk of damage to device through cleaning. Authors do not recommend reuse of IABs.
Zubaid et al. (2001) RCT, double blinded Kuwait Grade II	The safety and efficacy of previously used, resterilised balloon catheters for Percutaneous Transluminal Coronary Angioplasty (PTCA). Device manufacturer not stated.	Reused versus new coronary angioplasty balloon catheters. A total of 359 patients having 377 procedures with 178 procedures (mean age 54 years, 83% male) in reused and 199 (mean age 55, 76% male) in new catheter study arms. All patients undergoing coronary angioplasty but excluded those with total occlusion of unknown or 1+ month duration. And cardiogenic shock.	<ul style="list-style-type: none"> ▪ no significant differences in clinical or lesion characteristics between the two groups ▪ there were similarities between the two groups in first balloon failure, angiographic success rates, numbers of catheters used per lesion, amount of contrast, procedural time and numbers of adverse events at 30 days. 	<ul style="list-style-type: none"> ▪ randomisation method not well described ▪ the previous amount of device reuse (in vivo conditions) is not clear from the study ▪ cross-over of patients to other treatment arm due to procedural difficulties post-randomisation may cause significant differences in group baseline characteristics ▪ conclusion: authors affirm that in coronary angioplasty reused catheters are safe and effective.

Table 3. Evidence table on the safety and effectiveness of single-use device reuse – cardiovascular medical devices - PTCA catheters (continued)

Authors, study design, country evidence grading	Medical Device and study aim	Methods	Results	Conclusions
Shaw et al. (1999) Before and after study Canada Grade IV	The reuse of catheters for Percutaneous Transluminal Coronary Angioplasty (PTCA) on procedure time and clinical outcomes. Device manufacturer not specified.	Reused versus new PTCA balloon catheters. A total of 53 consecutive patients (mean age 64, 72% male) having PTCA with reused catheters prior to July 1996 compared with 54 consecutive patients (mean age 65, 80% male) having PTCA with single use catheters after. Retrospective chart review. Excluded were patients undergoing atherectomy and whose PTCA was abandoned.	<ul style="list-style-type: none"> ▪ no significant differences between patient groups in terms of the number of catheters used, angiographic success rates and hospital complications ▪ non-significant trend for longer procedure time and fluoroscopy for SUD group and no difference after controlling for case severity and use of stents. 	<ul style="list-style-type: none"> ▪ because of the risk of transmission of Creutzfeldt Jakob disease (CJD), Quebec province stopped reuse of PTCA catheters in July 1996. Up to this the maximum use of 4 times for balloon and 2 times for guide catheters was permitted ▪ the actual amount of reuse (in vivo conditions) unknown in reuse patient group but limitation of reuse group as one in four catheters were new ones ▪ author's conclusion: PTCA catheter reuse is not associated with disease transmission and should be advocated.
Ma et al. (2003) Prospective case series (laboratory research) Canada Grade IV	To investigate with an in vitro experiment the cytotoxicity of single-use polyurethane (PU) electrophysiology catheter extracts on macrophages after their re-sterilisation. PU-based single-use catheters Cordis (Miami, FL, USA).	Three sterilisation methods were compared: steam autoclave, ethylene oxide (EtO), hydrogen peroxide plasma Sterrad® - 100S system (Advanced Sterilisation Products, J&J, Irvine, CA, USA). Catheters cut into 10cm pieces and processed 1 or 10 cycles then 72-hour extraction tissue culture. A J774 mouse macrophage cell line (ACTT, Rockville, MD, USA) used. Extractions of processed catheters for both 1 and 10 cycles were used for cytotoxicity tests and compared with controls sterilised once. Controls were samples of catheters sterilised once and cut into pieces and decontaminated.	<ul style="list-style-type: none"> ▪ the viability of cells varied from 90% to 99% in relation to incubation time and the number of sterilisations ▪ no significant difference based on the sterilisation procedure ▪ the number of cycles was related to significant effects on J774 macrophages and inhibitory effect on cell growth observed ▪ extract obtained after resterilisation had low cytotoxic effects on J774 macrophages (cell mortality under 10%). 	<ul style="list-style-type: none"> ▪ author's conclusion: although significant changes were evident between control and processed samples and among processed samples a single reprocessing of PU-based catheters may not lead to significant changes in cytotoxicity.

Table 3. Evidence table on the safety and effectiveness of single-use device reuse – cardiovascular medical devices – catheters

Authors, study design, country evidence grading	Medical Device and study aim	Methods	Results	Conclusions
Luijt et al. (2001) Prospective case series (laboratory research) Netherlands Grade IV	To determine with an in vitro study the theoretical risk of viral infection transmission during catheter reuse. Device manufacturer not specified.	Deliberate contamination of 20 5F balloon catheters of varying sizes which were reprocessed (cleaned and glutaraldehyde sterilised) and subjected to simulated reuse. The presence of residual virus (DNA adenovirus-2 and RNA enterovirus-II) determined by cell culture and polymerase chain reaction (PCR). Tested at four different stages of experiment.	<ul style="list-style-type: none"> ▪ post-sterilisation infectious enterovirus was detectable in 10% of samples and 20% of samples contained detectable enterovirus RNA ▪ post-simulated reuse, endovirus was cultured from 10% of samples and 60% of the samples were enterovirus PCR positive and 10% contained detectable adenovirus DNA ▪ post-sonification of catheter tips no infectious virus found. Enterovirus RNA found in 20% of samples and adenovirus DNA in 30% of samples. 	<ul style="list-style-type: none"> ▪ author's conclusion: in vitro study demonstrates that even after strict cleaning and sterilisation, traces of virus were still present in some catheters. Reuse is unsafe and is not recommended.
Granados et al. (2001) Prospective case series (laboratory research) Spain Grade IV	Identification of differing material parameters in PVC catheters from reprocessing that could present health risks when reused in different patients. Manufacturer of devices not specified.	Hospital-reprocessed central venous catheters were obtained from a number of healthcare institutions. One trademark device selected, items used 8 and 24 times and compared with new ones. Recycling protocol included collection, rinsing, sent to reprocessing facility for cleaning refurbishment, inspection, re-packaging, Ethylene-oxide (ETO) sterilisation, air-wash and vacuum. Recycled catheters tested using Supercritical Fluid Extraction (SFE), Gas Chromatography, Scanning Electron Microscopy (SEM), Gel permeation Chromatography (GPC), Dynamic Mechanical Analysis (DMA).	<ul style="list-style-type: none"> ▪ successive catheter recycles were shown to increase plasticizer loss, increase glass transition temperature, small decrease in average molecular weight, increased surface roughness, increased appearance of surface grooves. 	<ul style="list-style-type: none"> ▪ author's conclusion: these biomaterial parameter changes suggest that reuse can alter the original device performance and possible adverse clinical events.

Table 3. Evidence table on the safety and effectiveness of single-use device reuse – cardiovascular medical devices – argon beam coagulation probe/angioscope

Authors, study design, country evidence grading	Medical Device and study aim	Methods	Results	Conclusions
Roach et al. (1998) Prospective case series (laboratory research) USA Grade IV	To determine whether or not argon beam coagulation probes can be reprocessed safely with their function or material properties being compromised. Manufacturer of the 10 probes used in study (2.3mm diameter, 220cm length), the ERBE APC 300, ERBE Inc., (Marietta, GA, USA).	Ten unused Argon Plasma Coagulation (APC) probes set a baseline coagulation depth on a piece of beefsteak 1.5cm sq for 60s. Probes contaminated with <i>Bacillus subtilis</i> spores, cultured, and cleaned manually. Probes packaged and individually and gas sterilised using ethylene oxide (EtO), blown dry. Probes were re-cultured to check sterilisation, inspection for damage and electrical integrity (coagulation on beefsteak). Process repeated nine times (10 trials).	<ul style="list-style-type: none"> ▪ all of the 10 probes completed the 10 testing sessions, though one split but remained functional ▪ electrical integrity was maintained in all devices for all 10 sessions ▪ colonies of <i>Bacillus subtilis</i> spores grew on all probes after contamination but none were detected after (EtO) sterilisation ▪ significant savings would be made from 10 uses clinically and less so for 5 clinical uses. 	<ul style="list-style-type: none"> ▪ author's conclusion: reused APC probes remained sterilised with a combination of cleaning and EtO sterilisation, 90% of probes remained functional and 100% maintained electrical integrity after 10 uses. APC's can be safely and effectively used up to 10 times.
Chaufour et al. (1999) Prospective case series (laboratory research-animal experimentation) Australia Grade IV	To assess the risk of nosocomial infection after the reuse and reprocessing of disposable angioscopes that are either properly or improperly cleaned before disinfection and sterilisation. 13 angioscopes tested, four from Edwards LIS (size 2.3 mm; Baxter Healthcare, Irvine, CA, USA) and 9 Intramed PF 28 (size 1.5 mm to 2.8 mm (Intramed, San Diego, USA).	An angioscopic examination of the external jugular vein was carried out on 38 ducks infected with hepatitis B virus (DHBV). After use angioscopes were air dried, samples were obtained by flushing the channel with 5ml of solution. These were obtained straight after drying (control), after flushing with 5ml water, after disinfection with 2% glutaraldehyde for 5, 10, and 20 minutes, after ethylene oxide gas sterilisation. Angioscopes were either pre-cleaned or improperly cleaned before disinfection and sterilisation. The infectivity of the angioscopes was assessed by inoculating day old ducklings (n=231) with samples.	<ul style="list-style-type: none"> ▪ from duckling liver samples, all 38 controls became infected from samples ▪ the frequency of infection was reduced to 93% (14 of 15) with samples from having flushed angioscopes in 5ml of water ▪ after the use of samples from improperly cleaned angioscopes transmission rate was 90% (9 of 10), after 5 and 10 minutes in 2% glutaraldehyde, after 20 minutes 6% (2 of 35) transmission. Even with ethylene oxide sterilisation (2 of 35) ducklings were infected ▪ there was no transmission to ducklings after the use of samples from any of the properly cleaned and disinfected and sterilised angioscopes. 	<ul style="list-style-type: none"> ▪ author's conclusion: with proper cleaning and sterilisation reused angioscopes do not pose a risk for disease transmission. If angioscopes are improperly cleaned then duck hepatitis B virus (DHBV) can survive in spite of glutaraldehyde disinfection or ethylene oxidation sterilisation it is hypothesized that a narrow lumen or residual protein shielding within the lumen may undermine effective inactivation of (HBV) microorganisms on angioscopes.

Table 3. Evidence table on the safety and effectiveness of single-use device reuse – cardiovascular medical devices - ablation catheters

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Ayzman et al. (2002) Prospective case series (laboratory research) USA Grade IV	The evaluation of effects of reuse on temperature sensing ability and mechanical deflection capability in current generation radio frequency ablation catheters. Devices and manufacturers were Steerocath (Boston Scientific EPT – San Jose, CA, USA) and Celsius (Cordis-Webster Raritan, NJ, USA).	An in vitro study of 24 ablation catheters (12 new and 12 used). Temperature sensing deviation of catheters measured in a heated saline bath. The angle of deflection of digitally scanned catheters at 75% and 100% handle deflection also measured. A used catheter reprocessing protocol of cleaning, visual inspection, tested for deflection ability and electrical continuity, repackaging, resterilisation. New and used (average 2.3 uses) catheters compared.	<ul style="list-style-type: none"> ▪ no significant difference in new and used catheters in temperature sensing ▪ no significant difference in new and used catheters on angle of deflection at 75% and 100%. 	<ul style="list-style-type: none"> ▪ author's conclusion: there was no overall significant difference in temperature sensing accuracy and deflection angle of new and used ablation catheters. There were instances of differences in deflection characteristics which should be screened for in reprocessed catheters prior to their reuse.
Bloomstrom-Lundqvist (1998) Prospective observational study (laboratory research) Sweden Grade IV	The safety issues around reusing radio frequency ablation catheters with temperature control and validation protocol and reprocessing guidelines. Ablation catheters (74) with temperature control Cordis-Websters (65) (Cordis-Webster, Baldwin Park, CA, USA) and Osypkas (9) (Osypka Cerablate, Sulzer Medica, Grenzach-Wyhlen, Germany).	From September 1994 to December 1997, a total of 74 deflectable ablation catheters with temperature control (Cordis-Websters and Osypkas) were each used during an average of 7.6 ablation sessions. Catheter tests included: visual inspection, impedance measurements, catheter deflection capability, integrity of the thermistor and thermocouple. Catheters resterilised by Sterrad® system (Advanced Sterilisation Products, J&J, Irvine, CA, USA) after each use.	<ul style="list-style-type: none"> ▪ a total of 41 catheters were rejected using the protocol and guidelines after an average of 9.1 uses. Most failures occurred at any time during reuse ▪ the major reasons for rejection were inaccurate temperature measurements, breakage/defect with internal pulling wire, disturbance or loss of electrogram, deflection capability ▪ no major catheter failures or adverse clinical outcomes ▪ no infections reported. 	<ul style="list-style-type: none"> ▪ the effect of sterilisation alone not studied ▪ patient numbers, characteristics and clinical characteristics of usage not reported ▪ temperatures tested at time of catheterisation showed no failure ▪ author's conclusion: a strict validation protocol and quality control guidelines ensured that these types of ablation catheters sustain repeated reuse and resterilisation without patient harm.

Table 3. Evidence table on the safety and effectiveness of single-use device reuse – cardiovascular medical devices – perfusion cannulae

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Bloom et al. (1997) Prospective case series (laboratory research) USA Grade IV	<p>To determine the feasibility of reprocessing and reusing venous and arterial disposable perfusion cannulae.</p> <p>To test clinically used and clinically simulated used devices for the efficacy of the sterilisation process, material changes, functional integrity, and biocompatibility. To test an in vivo device performance in an animal model to assess the feasibility of reusing disposable perfusion cannulae.</p> <p>The cannula types were the Research Medical Incorporated (RMI, Salt lake City, Utah) dual and single-stage venous return cannulas (32F and 36F) and the 3M/Sarns (St Paul, Minn) soft flow 8.0 mm models.</p>	<p>Single and dual stage cannulae from two manufacturers tested when either new, after first clinical use, or after initial use plus up to nine simulated reuses.</p> <p>Reuse simulated by various conditioning techniques. Cannulae were decontaminated and sterilised (peracetic acid-based liquid chemical) after each reuse. Validation by using microbial testing after disinfection for five consecutive cycles.</p> <p>Devices tested for physical changes, functional integrity, biocompatibility, in vivo performance in sheep. Cost analysis.</p>	<ul style="list-style-type: none"> ▪ the perfusion cannulae tested were effectively sterilised and were shown to be safe for reuse within the limits five cycles tested for materials evaluations ▪ no significant clinical differences between new and reused cannulas up to nine simulated reuses ▪ reusing cannulas up to four times is estimated to reduce the cost per procedure by up to 64%. 	<ul style="list-style-type: none"> ▪ author's conclusion: from the data evaluated perfusion cannulas can be effectively and safely reused up to five times. Some limited reuse is technically possible and cost effective.

Table 4. Evidence table on the safety and effectiveness of single-use device reuse – anaesthesia medical devices

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Daggan et al. (1999) Prospective case series USA Grade IV	To determine if the new Filta-Therm® filter prevents contamination and allows reuse of breathing circuit equipment. The breathing circuit was the reusable Multipac and filter was the Filta-Therm® filter (Intersurgical, Inc., Liverpool, NY, USA).	52 patients (18-75 years) undergoing surgical procedures. Each morning a new breathing circuit was assembled. The filter, mask and elbow was changed between patients but not the circuit. Filter placed on Y-piece and elbow of the breathing circuit. Prior to anaesthesia bacterial samples obtained from Y-piece, inspiratory and expiratory ports of breathing circuit. Following anaesthesia samples obtained at the Murphy eye of endotracheal tube and Y-piece and incubated for 48-hours.	<ul style="list-style-type: none"> ▪ cultures taken prior to anaesthesia showed no growth ▪ all 52 cultures taken after anaesthesia showed contamination at the endotracheal tube with various organisms while all 52 samples from the Y-piece showed negative results. 	<ul style="list-style-type: none"> ▪ author's conclusion: the Filta-Therm® filter prevents bacterial contamination and allows reuse of breathing circuit up to at least two times and would result in significant cost savings.
Vežina et al. (2001) Prospective case series (laboratory research) Canada Grade IV	To evaluate with an in vivo study the bacterial filtration efficacy of an anaesthesia filter (DAR Barrierbac S®) to allow the reuse of the same anaesthesia breathing circuit on more than one patient. The breathing filter studied was the DAR Barrierbac S® (Mallinckrodt DAR, Mirandola, Italy).	Over a 26-week period 2001 breathing filters were studied from all daytime general anaesthesia cases. Each filter from sterile package aseptically attached to Y-piece of a new sterile disposable clear anaesthetic breathing circuit (22mm * 183 cm) (Trudell Medical Limited, London Ontario Canada). Filter removed after anaesthesia and both sides swabbed for bacterial culture (48-hours).	<ul style="list-style-type: none"> ▪ cultures showed contamination on patient side of filter of 104 filters ▪ cultures showed positive bacterial passage through the membrane in 2/2001 filters, a clinical efficacy of 99.9% accounting for only those filters subjected to documented bacterial challenge the in vivo filtration efficacy was 98.1%. 	<ul style="list-style-type: none"> ▪ author's conclusion: using sterile single use breathing filter while reusing the anaesthesia breathing circuit results in a cross-contamination rate of less than 1/250 cases.

Table 4. Evidence table on the safety and effectiveness of single-use device reuse – sphincterotomes

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Kozarek et al. (1997) Prospective case series (laboratory research) USA Grade IV	An in vitro study to test the durability, electrical integrity and ability to be adequately cleaned both manually and with ethylene oxide of sphincterotomes after contamination with 10 ⁵ and 10 ⁶ <i>Myco-bacterium chelonae</i> . Sphincterotomes were manufactured by Wilson-Cook Medical Inc (Winston-Salem, N.C, USA).	10 braided wire sphincterotomes were studied (five 5F one-time use, single lumen (UTS-30) and five 6F wire-guided, double-lumen (CT30). Baseline tests of electrical power output were performed then each device was contaminated. Devices were manually cleaned, dried and packaged and gas sterilised with ethylene oxide (EO). Cultures were obtained twice following (EO). Then process (use, contamination, cleaning) repeated 9 further times for each device.	<ul style="list-style-type: none"> ▪ seven out of ten sphincterotomes remained intact with reuse and cleaning ▪ three 6F sphincterotomes had wire fracture after 4 to 8 uses ▪ electrical integrity remained intact up to time breakage in all sphincterotomes as measured by electrosurgical analyzer ▪ no device had evidence of organisms following manual cleaning and EO sterilisation but not the case with other cleaning methods. 	<ul style="list-style-type: none"> ▪ author's conclusion: disposable Sphincterotomes have the potential to be reused safely.
Kozarek et al. (1999) Prospective case series (laboratory research) USA Grade IV	To prospectively define the number of uses obtained from two types of sphincterotomes, the reasons for dysfunction and complications arising from reuse. Sphincterotomes were manufactured by Wilson-Cook Medical Inc (Winston-Salem, N.C, USA).	154 braided wire sphincterotomes were studied (27 5F UTS-30) and (127 6F CT30) that are marketed for one time use were used for up to 10 times. After use (as cannulating/cutting devices) they were manually reprocessed, repackaged and gas sterilised for reuse. Both new/used sphincterotomes were discarded before/during/after procedure or after 10 uses. Data on dysfunction, infectious complications, and cost-savings collected over 12 months.	<ul style="list-style-type: none"> ▪ mean number of uses was 3.4 times per device ▪ broken of still cutting wire main reason for device being discarded ▪ two patients experienced infectious complications, both received new devices and had unrelieved ductal obstructions ▪ significant cost savings. 	<ul style="list-style-type: none"> ▪ author's conclusion: double channel sphincterotomes marketed for single use can be reused safely if they undergo rigorous manual reprocessing and ethylene oxide sterilisation.

Table 5. Evidence table on the safety and effectiveness of single-use device reuse – airway devices used for emergency intubation

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Lipp et al. (2000) Prospective case series (laboratory research) Germany Grade IV	To analyse the safety and validity of reprocessing Combitubes® devices used in emergency endotracheal intubation and difficult airway management. Combitubes® were manufactured by Kendall-Sheridan (Argyll, N.Y, USA).	Examination process included: <ul style="list-style-type: none"> ▪ microbiological examinations of reprocessed contaminated unused tubes (4) ▪ clinical use of Combitubes® ▪ reprocessing by company of used Combitubes® with standard methods (cleaning, disinfection, final inspection, sterilization) (2 devices reused and reprocessed 4 times and 1 unused device) ▪ microstructure and material science examinations (1 unused and 1 reprocessed device). 	<ul style="list-style-type: none"> ▪ microbiological examinations of multiple reused and reprocessed Combitubes® found no test organisms ▪ microbial reduction of 4 and 5 log levels compared with non-reprocessed tubes ▪ non-significant alterations to topographical and chemical surface between new and reprocessed devices ▪ material science tests showed that cuff burst pressures were not different between new and multiple reprocessed devices. 	<ul style="list-style-type: none"> ▪ author's conclusion: results show decontamination process to be adequate and safe and that no significant alterations to devices resulted from multiple reuse and reprocessing.
Wilson et al. (2000) Retrospective investigative study USA Grade IV	An investigation into a suspected outbreak of lower respiratory tract infections caused by <i>Aureobasidium</i> species (a rare, dematiaceous mold). The automated bronchoscope disinfection machine manufactured by Steris Corporation (Mentor, OH, USA).	An outbreak investigation was conducted using standard procedures. A database source of all <i>Aureobasidium</i> isolates in past 6 years compiled, medical records examined. Ten bronchoalveolar lavage cultures from nine patients grew the <i>Aureobasidium</i> mold.	<ul style="list-style-type: none"> ▪ no patient was judged to have had infection due to <i>Aureobasidium</i> either before/after bronchoscopy ▪ <i>aureobasidium</i> isolates were not associated with any one bronchoscope ▪ observation of bronchoscopy procedure showed that single-use plastic stopcocks were reused on different patients and no record of how many times reused ▪ after each use stopcocks were reprocessed in an automated disinfection machine for bronchoscopes ▪ culture from the stopcocks after disinfection showed significant growth of <i>Aureobasidium</i> ▪ culture of fluid from disinfection machine was negative ▪ reuse of stopcocks was stopped and in the 6-months following no <i>Aureobasidium</i> isolated. 	<ul style="list-style-type: none"> ▪ outbreak only alerted from the rarity of the organism identified which has been implicated as causative agent in pneumonia and other serious illnesses ▪ no information on incidence rates retrospective study using laboratory and patient medical records ▪ author's conclusion: reuse of medical devices labelled single-use can expose patients.

Table 6. Evidence table on the safety and effectiveness of single-use device reuse – disposable plastic trocars

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Chan et al. (2000) Prospective case series (laboratory research) Hong Kong China Grade IV	To undertake an in vitro experiment to determine whether or not disposable plastic trocars can harbor infectious viruses. Trocars manufactured by Ethicon Endo-surgery Inc, (Cincinnati, OH, USA).	Four (10/11 mm) disposable trocars were exposed to contaminated horse blood with high/low viral concentrations of herpes simplex virus type 1 (HSV1) and similarly 4 others with polio virus type 1 for 2 hours at room temperature. Viral cultures taken. Trocars subsequently underwent cleaning and resterilisation process with low-temperature steam and formaldehyde at 80°C for 3 hours and then viral cultures repeated.	<ul style="list-style-type: none"> ▪ a cytopathic effect was observed in all trocars before but not after sterilisation at both high/low concentrations of HSV-1 ▪ a cytopathic effect from high concentrations of polio virus was observed in all trocars before and in 50% of trocars after sterilisation. 	<ul style="list-style-type: none"> ▪ horse blood and viruses used as way of simulating worse case scenario ▪ author's conclusion: the reuse of disposable trocars cannot be recommended. They are difficult to clean and may harbor infectious viruses.
Gundogdu et al. (1998) Pseudo-randomised controlled study Turkey Grade III-2	To conduct a prospective study examining the infection risk of high-level sterilisation of disposable plastic trocars in order to determine safety and economic benefits. Trocars manufacturer not stated.	45 patients (mean age 48 years) underwent laparoscopic cholecystectomy having a diagnosis of cholecystitis. In 30 of these cases, the trocars used after disinfection in alkalized 2% glutaraldehyde solution. In the other 15 cases new trocars were used and acted as a control group. Eight culture samples taken from trocars, laparoscope, glutaraldehyde solution, and umbilicus pre-operatively and from bile in the gall bladder, peritoneal lavage fluid and epigastric and umbilical incisions postoperatively.	<ul style="list-style-type: none"> ▪ one of the disinfected trocars yielded a culture-positive result ▪ no culture-positive results found in samples from laparoscope, glutaraldehyde and epigastric incisions ▪ culture-positive results were found in 11 cases at the umbilicus, one at the peritoneal lavage and one at the umbilical incision ▪ no patients had infection at wound site or intra-abdominally. 	<ul style="list-style-type: none"> ▪ authors state that patients were randomly assigned but no information provided surgeons but not nurse blinded to which patients received new and used trocars ▪ author's conclusion: plastic disposable trocars can be reused safely after high-level disinfection.
Uluap et al. (2000) Randomised controlled study (laboratory research) Turkey Grade III-2	To perform a complex in vitro experimental study to determine whether or not it is possible to reesterilize disposable laparoscopy trocars in a hospital setting. Trocars manufacturer not specified.	Forty disposable trocars divided up into two equal groups. Group 1 contaminated with bacteria and yeast and Group 2 with hepatitis B virus, both contaminated under controlled conditions these groups further divided into 2 equal sub-groups. Disinfection of group A with 2% glutaraldehyde and group B with ethylene oxide (EO) then samples obtained for bacterial and virus detection using polymerase chain reaction (PCR).	<ul style="list-style-type: none"> ▪ persistent contamination after sterilisation with bacterial and yeast cultures identified in 3 instruments in group 1A and 2 in group 1B ▪ contamination with hepatitis B virus was negative in group 2A but positive in group 2B. 	<ul style="list-style-type: none"> ▪ care taken to simulate contamination as may occur in actual laparoscopic operation ▪ author's conclusion: in-hospital reprocessing and reuse of disposable laparoscopic trocars should be avoided. Disinfection for multiple use of trocars with complex structure not effective as residual disease transmission may occur.

Table 7. Evidence table on the safety and effectiveness of single-use device reuse – biopsy forceps

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Cogdill et al. (1998) Prospective case series (laboratory research) USA Grade IV	To determine whether or not reused single-use biopsy forceps are being safely and effectively reprocessed for reuse. Biopsy forceps manufacturer not stated.	Three groups of single-use biopsy forceps (19) were tested for bioburden, sterility, performance and quality assurance after having been reprocessed by a third-party reprocessor. Cleaning, sterilisation and validation standards used as defined by Association for the Advancement of Medical Instrumentation (AAMI). Group A (5 devices) sent to a contract lab for bioburden/sterility testing Group B (1 device) suspected of blood contamination Group C (13 devices) evaluated in-house for performance and quality assurance.	<ul style="list-style-type: none"> ▪ four out of five devices in group A were found to be non-sterile ▪ several areas of visual contamination identified, confirmed as blood ▪ some microvase devices in group C showed degradation in quality aspects – i.e., physical properties. Nearly 40% of these devices would have been rejected in meeting the Boston Scientific/ Microvase quality control standards. 	<ul style="list-style-type: none"> ▪ based on abstract only ▪ author's conclusion: single-use biopsy forceps were not safe for reuse after having been reprocessed as they were not adequately cleaned nor had sterility been achieved.
Hambrick (2001) Prospective case series (laboratory research) USA Grade IV	To determine whether or not two types of single-use devices (disposable biopsy forceps and snares) can be effectively cleaned and sterilised to allow for safe reuse in subsequent patients. All devices were manufactured by Boston Scientific/Microvase Endoscopy, (Natick MA, USA).	A total of 23 biopsy forceps and two snares were submitted for testing after being used once in endoscopic procedures. Cleaning and sterilisation included of a rinse in an enzymatic cleaner, shipping to third-party facility, cleaning/sterilisation by ISO 9002 certified processor using AAMI guidelines. An independent lab tested sterility of reprocessed devices using bioburden/sterility tests, United States Pharmacopoeia (USP) test and bacterial endotox in (limulus Amebocyte lysate (LAL)) testing.	<ul style="list-style-type: none"> ▪ the failure rate in bioburden/sterility testing was 10% and in USP sterility testing 70% attributed to design features, absence of standards for reprocessing devices and single-use manufacturer design ▪ current AAMI guidelines for the design and manufacture of devices suitable for reprocessing were not met. 	<ul style="list-style-type: none"> ▪ author's conclusion: the medical devices tested fell significantly below established standards for sterility despite rigorous selection of a reprocessor and validated reprocessing.

Table 7. Evidence table on the safety and effectiveness of single-use device reuse – biopsy forceps (*continued*)

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Heeg et al. (2001) Prospective case series (laboratory research) Germany USA Grade IV	To determine whether or not the reprocessing of single-use biopsy forceps, papillotomes and a reusable stone retrieval bucket meet regulatory standards for sterility and materials standards as with new devices. Device's manufacturer(s) not specified.	Single-use and reusable biopsy forceps and papillotome devices were contaminated with human blood containing technetium 99-radiolabelled. Cleaning, sterilisation and validation standards used as defined by Association for the Advancement of Medical Instrumentation (AAMI). Devices cleaned following hospital practices for manual cleaning Cleaning (11 incl 1 control), disinfection evaluation (8 incl 2 sterile controls), sterilisation with steam and EtO evaluation (20 incl 2 controls), bio-burden testing. Gamma counts determined before/after cleaning to identify contaminants, light scanning electron microscopy, X-ray photoelectron spectroscopy for quantification of contaminants on materials. Single-use device results compared with similar reusable devices.	<ul style="list-style-type: none"> ▪ all of the devices were still contaminated after cleaning, however single-use devices and the stone bucket were more heavily contaminated than reusable forceps and papillotomes ▪ cleaning procedures tended to enhance the distribution of contaminants into the lumens of disposable devices ▪ there were decreased concentrations of silicon and increased concentrations of carbon and nitrogen which may suggest that silicon lubricant had been removed ▪ sterilisation effectively removed challenge microorganisms from reusable devices but not single-use devices. 	<ul style="list-style-type: none"> ▪ author's conclusion: no single-use devices were effectively cleaned, sterilised, or disinfected presenting opportunities for infections from viruses and nosocomial organisms.

Table 7. Evidence table on the safety and effectiveness of single-use device reuse – biopsy forceps (*continued*)

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Kinney et al. (2002) Prospective case series (laboratory research) USA Grade IV	To evaluate the risk of contamination of single-use biopsy forceps at various levels of endoscope reprocessing. Biopsy forceps manufacturer Radial Jaw Microvasive Endoscopy Inc (Natick, Mass), Colonoscopes CF140, CF160 Series Olympus America Inc (Melville, NY, USA).	Fifty disposable biopsy forceps were passed through the accessory channels of 10 colonoscopes subjected to various levels of reprocessing: <ul style="list-style-type: none"> ▪ prior to use in patients (baseline) straight after colonoscopy (contamination confirmation) ▪ after manual cleaning and flushing of accessory channel (test if significantly decreases bioburden) ▪ after manual cleaning and 2 minute soak in 2% glutaraldehyde (test if adequate cleaning time) ▪ similar to above but 20 minute soak ▪ forceps were then sealed in sterile plastic bags (thioglycollate medium), vacuum filter and filters cultured. 	<ul style="list-style-type: none"> ▪ a total of 50 aerobic and 50 anaerobic cultures were performed ▪ colonies forming units of GI flora grew on 19/20 plates from biopsy forceps passed through colonoscopes immediately after use ▪ GI flora were found on 5/20 plates after manual cleaning of colonoscopes ▪ no GI flora was found on forceps after the colonoscopes had been soaking in glutaraldehyde for 2 and 20 minutes. 	<ul style="list-style-type: none"> ▪ author's conclusion: single-use biopsy forceps are susceptible to contamination from improperly cleaned endoscopes, high-level disinfection of colonoscopes prevented forceps contamination at baseline an after reprocessing, adequate reprocessing of endoscopes are an important factor in preventing biopsy forceps being contaminated and cross-patient infection.

Table 7. Evidence table on the safety and effectiveness of single-use device reuse – biopsy forceps (*continued*)

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Roth et al. (2002) Prospective case series (laboratory research) Germany Grade IV	<p>To determine whether or not the reprocessing of single-use laparoscopic surgery devices meet regulatory standards for sterility and materials standards as for new devices and therefore present a possible risk for patients of infection.</p> <p>Devices in stage 1 described as: Ethicon Endosurgery Endopath DCS 12, Ch.Nr M4FF41: 5mm curved scissors for monopolar cautery, 300mm working length.</p> <p>Ethicon Endosurgery Ultracision Harmonic Scalpel LCS K5, Ch.Nr M4HY67: 15mm active blade. 5.5 mm in diameter, 320 mm working length.</p> <p>Ethicon Endosurgery Ultracision Harmonic Scalpel LCS 6S, Ch.Nr N4HV53: 15mm active blade. 10 mm in diameter, 340mm working length.</p>	<p>A two stage study: stage 1 laboratory tests of single-use laparoscopic dissection devices with simulated use and reprocessing and stage 2 a variety of SUDs that had been clinically used and reprocessed.</p> <p>Stage 1: Devices contaminated with human blood containing technetium 99-radiolabelled, cleaned and simulated clinical use, cleaning, sterilisation and assessment of cleaning efficacy with light microscopy, scanning electron microscopy (SEM), and X-ray photoelectron spectroscopy (XPS), evaluation of disinfection using microbial testing after disinfection.</p> <p>Stage 2: A variety of devices (114) collected from different hospitals across Europe and had been reprocessed following clinical use. These were tested for sterility etc only items similar to those tested in stage 1 included.</p>	<ul style="list-style-type: none"> ▪ in stage 1 of the study all devices remained contaminated after cleaning but were disinfected ▪ sterilisation did not remove all traces of the challenge organisms ▪ for stage 2 of the study the examination of clinically used and reprocessed devices found damaged sterile packaging (11%), incomplete/missing device parts (33%), functionality criteria not met (54%), contamination evident in all devices from tests and 40% of devices tested were non-sterile after sterilisation. 	<ul style="list-style-type: none"> ▪ cleaning, sterilisation and validation standards used as defined by Association for the Advancement of Medical Instrumentation (AAMI) ▪ author's conclusion: no single-use devices were effectively cleaned, sterilised, or disinfected, presenting opportunities for infections from viruses and nosocomial organisms.

Table 8. Evidence table on the safety and effectiveness of single-use device reuse – general hospital equipment

Authors Country Evidence Grading	Medical Device and study aim	Methods	Results	Conclusions
Dirschl et al. (1998) Retrospective before and after study USA Grade IV	To determine the cost-effectiveness of a programme for the reuse of orthopaedic external fixator components used in and to compare the rate of complications associated with fixators before and after the implementation of the programme The fixator devices were manufactured by the following companies: <ul style="list-style-type: none"> ▪ Synthes (Paoli, PA, USA) ▪ Orthofix (Parsippany, NJ, USA) ▪ Hofmann (Rutherford, NJ, USA) ▪ Ace Fisher (El Segundo, CA, USA) ▪ EBI (Parsippany, NJ, USA) ▪ Joint Biomechanics (Sacramento, CA, USA) ▪ Richards (Memphis, TN, USA). 	After patient use fixators were cleaned (disassembled and autoclaved) and examined by a nurse responsible for the programme. Components in good condition returned to hospital stock for sterilisation and reuse. None of these components use more than 3 times. Components in poor condition were discarded. All patients having external fixation devices applied 15-months either side (69 and 65 devices) of beginning of programme date included. Data extracted by external chart review.	<ul style="list-style-type: none"> ▪ there was 32% decrease in mean hospital charge for a fixator and hospital cost decreased by 34% as a result of the reuse programme ▪ no patient had mechanical failure of a new or reused fixator ▪ there were no differences in reoperation and complication rates comparing before/after. 	<ul style="list-style-type: none"> ▪ author's conclusion: reuse programme of carefully selected fixator components is safe and recommend institutions reusing devices develop a specific programme for reuse.

OVERVIEW

Study designs and levels of evidence

The evidence tables summarise the reviewed literature that satisfies the study inclusion and exclusion criteria and examines the evidence regarding the safety and effectiveness of the reuse of SUDs. Overall, the level and quality of the study evidence for the safety and effectiveness of reuse of SUDs was almost entirely restricted to lower Level IV evidence according to the NHMRC hierarchy of evidence, the most prevalent study designs being prospective/retrospective case series and before/after designs. There were also three randomised controlled trials (one grade II and two grade III-2 evidence). Most of the included studies were laboratory research studies evaluating surrogate endpoints such as device contamination, device integrity and performance as outcomes rather than patient oriented outcomes such as device failure during use and infection transmission. Those laboratory studies with a comparator commonly used identical new single-use medical devices for comparison with the effects of reprocessing and/or reuse on reused devices. Those studies involving patients compared patients receiving reprocessed SUDs with those receiving identical new SUDs for the same procedure.

Overall assessment of evidence regarding the safety and effectiveness of the reuse of medical devices labelled ‘single-use only’

The evidence for the safety and effectiveness of the reuse of medical devices labeled ‘single-use only’ is indirect as it involves the synthesis of evidence derived largely from studies based on laboratory experimentation combined with evidence from a limited number of studies on the exposure of patients to reprocessed and reused single-use medical devices. There is therefore some difficulty in defining a direct causal link between patient exposure to contaminated/malfunctioning reprocessed SUDs and adverse patient outcomes. The laboratory experimentation studies are disease orientated evidence (DOE), often using mechanistic explanations and laboratory values to evaluate surrogate endpoints rather than evaluating outcomes directly in patients (patient oriented evidence that matters-POEMs) such as changes in morbidity or mortality. There is an overall lack of patient outcome evidence to support general clinical recommendations regarding the reuse of SUDs.

The studies considered are both for and against the reuse of SUDs. The safety and effectiveness of specific SUDs is summarised in **Table 9 (pages 37-38)** and in the evidence tables above.

Overall, the majority of studies reviewed here were against reuse and did not recommend reprocessing and reuse of SUDs. The arguments against reuse were that it is difficult to generalise about reuse as the effects of reprocessing and reuse are model specific (Brown et al. 2001), the results of laboratory tests suggest material parameter changes and alteration of original device performance and that there is deterioration of mechanical properties from reprocessing/re-sterilisation that could lead to adverse clinical events (Granados et al. 2001; Unverdorben et al. 2003). There was also ineffectual cleaning and re-sterilisation with tests showing residual bio-material and organisms (Yang et al. 1997). This was partly due to the difficulties associated with effectively cleaning devices with complex structures and the retention of organisms and the risk of damage in doing so (Luijt et al. 2001). Tested devices, despite cleaning, disinfection, and sterilisation under strict guidelines were found to contain residual organisms and present potential infection opportunities from viruses and nosocomial organisms (Chan et al. 2000; Uluap et al. 2000; Cogdill et al. 1998; Hambrick, 2001; Heeg et al. 2001; Kinney et al. 2002; Roth et al. 2002).

Although many of these findings are based on laboratory research, some studies involving patients concluded that there is a subjective relationship between recycling and reusing SUDs and patient health that cannot be determined (Vezina et al. 2001). The cause and effect of such research cannot be adequately demonstrated and that there is a lack of direct causal inference from the wider body of literature. Many different factors could contribute to adverse patient events during for example, surgery, not only the reuse of SUDs. It is therefore very difficult to determine and quantify until more rigorous studies are available and that until then, all reuse of SUDs should be banned.

However, some of the reviewed literature concluded that the reuse of some SUDs is safe in view of the lack of studies showing any association between reuse and adverse patient outcomes. Studies in favour of reuse conclude that with strict controls the reuse of specific SUDs is safe, effective and cost-effective (Browne et al. 1997; Zubaid et al. 2001; Dirschl et al. 1998). These studies have test results showing reprocessed SUDs free of residual bio-material and organisms, intact device integrity and maintained functionality, with no failures after repeated reuses and reprocessing (Bloomstrom-Lundqvist, 1998) and no patient harm (Daggan et al. 1999). Also, reuse and reprocessing in some cases can be safe and effective up to a limited specified number of times (Roache et al. 1998; Bloom et al. 1997). Several studies concluded that the cross-contamination rate was so low as to be of no clinical significance (Shaw et al. 1999; Vezina et al. 2001). Conditional reuse should be permitted after rigorous manual reprocessing and reesterilisation (Kozarek et al. 1999).

There has been over a decade of controversy surrounding the reuse of SUDs, due to the lack of rigorous scientific studies proving the safety and efficacy of reusing SUDs. It is generally agreed that there is a lack of data on the incidence of cross-infection and on the loss of device functionality from reprocessing procedures. The risks associated with the reuse of SUDs are not well documented. The possibility exists for injury but the incidence of such adverse events are under-reported due to a lack of surveillance and device tracking methods and the disincentive of reporting such events because of legal liability issues (Dunn, 2002b).

There are conflicting results in the literature concerning the safety and effectiveness of reusing SUDs, one side showing the safety and efficacy of reuse of some SUDs and others countering it. The literature reviewed in this Tech Brief confirms these conflicting findings. In view of the mixture of ‘for reuse’ and ‘against reuse’ research findings, to ultimately ensure patient safety “validation studies must be performed for each and every device and for each model” (Dunn, 2002a).

The following table summarizes the overall conclusions of the evidence tables by device category.

Table 9. Summary table of evidence by single-use medical device category

Table studies	Medical device	Conclusion of reuse
Study – Table 1		
Brown et al. (2001)	PTCA catheters	Difficulties generalising as model specific
Browne et al. (1997)	PTCA catheters*	Safe and effective under strict controls
Shaw et al. (1999)	PTCA catheters*	Safe and effective, should be advocated
Unverdorben et al. (2003)	PTCA catheters	Observed device deterioration
Zubaid et al. (2001)	PTCA catheters*	Safe and effective
Yang et al. (1997)	IAB devices	Difficulties in cleaning and potential device damage, do not recommend
Granados et al. (2001)	PVC catheters	Reuse can alter device integrity and performance
Luijt et al. (2001)	Balloon catheters	Evidence of residual virus after reprocessing
Ma et al. (2003)	Electro-physiology catheters	Evidence of cytotoxicity after reprocessing
Chaufour et al. (1999)	Disposable angioscopes	No evidence of infection transmission after reprocessing with proper reprocessing
Roach et al. (1998)	Argon plasma coagulation probes	Safe and effective reprocessing and reuse up to 10 times
Ayzman et al. (2002)	Ablation catheters	No evidence of significant changes in device integrity
Bloomstrom-Lundqvist et al. (1998)	Ablation catheters	Safe and effective with strict reprocessing guidelines

* denotes outcomes evaluated in patients

Table 9. Summary table of evidence by single-use medical device category (continued)

Table studies	Medical device	Conclusion of reuse
Study – Table 2		
Daggon et al. (1999)	Breathing circuit filter*	Safe and effective up to at least two times
Vežina et al. (2001)	Breathing circuit filter	Contamination of circuit in 1/250 cases, do not recommend
Study – Table 3		
Kozarek et al. (1997)	Sphincterotomes	Safe and effective with rigorous reprocessing standards
Kozarek et al. (1999)	Sphincterotomes	Safe and effective with rigorous reprocessing standards
Study – Table 4		
Lipp et al. (2000)	Airway device	Safe and effective from multiple reuse and reprocessing
Wilson et al. (2000)	Bronchoscopic stopcocks*	Potentially hazardous for patients with no quality control of reprocessing
Study – Table 5		
Chan et al. (2000)	Disposable trocars	Difficult to reprocess, do not recommend reuse
Gundogdu et al. (1998)	Disposable trocars*	Safe and effective after rigorous reprocessing
Uluap et al. (2000)	Disposable trocars	Difficult to reprocess, do not recommend reuse
Study – Table 6		
Cogdill et al. (1998)	Biopsy forceps	Reprocessing standards not met, devices not clean or sterile
Hambrick (2001)	Biopsy forceps	Reprocessing standards not met, devices not clean or sterile
Heeg et al. (2001)	Biopsy forceps	Reprocessing standards not met, devices not clean or sterile
Kinney et al. (2002)	Biopsy forceps	Reprocessing standards not met, devices not clean or sterile
Roth et al. (2002)	Biopsy forceps	Reprocessing standards not met, devices not clean or sterile
Study – Table 7	Medical device	Conclusion on reuse
Dirschl et al. (1998)	Orthopaedic external fixator components*	Safe and effective with strict guidelines

* denotes outcomes evaluated in patients

In summary, there is conflicting evidence in the literature reviewed regarding the safety and effectiveness of single-use device reuse. About half of the studies for cardiovascular medical devices concluded that the reprocessing and reuse of the SUDs under investigation was safe and effective under stringent controls, particularly in studies evaluating patients receiving PTCA catheters. Yet other studies identified evidence of residual organisms, bio-material and device deterioration after reprocessing and difficulties generalising study results because of model specificity. Similar findings were apparent for anaesthesia devices, airways devices, and disposable plastic trocars. The reprocessing and reuse of sphincterotome devices was considered safe and effective with proper reprocessing standards. Studies investigating biopsy forceps consistently showed that reprocessing standards were not met as the devices were not clean nor sterile.

Study limitations

The limitations of each specific study are not evaluated in the evidence tables. Instead a number of general limitations of the literature reviewed are outlined here.

The subjective way in which studies have been combined to assess the overall evidence. It was not possible to tabulate any one or a limited number of outcomes because of mixture of research findings and the fact that both surrogate and patient outcomes were measured using similar SUDs.

The absence of proof of evidence does not necessarily translate into proof of a lack of evidence and the indirect evidence available on the reuse of SUDs from laboratory studies clearly suggests that single-

use devices which are reprocessed still retain harmful organisms and bio-material and changes to device integrity and functionality.

In the studies reviewed only single device models, and certain aspects of their functionality and properties were tested, as were only specific tests done for certain pathogens and only specific protocols followed for reprocessing. The immense diversity in the SUDs tested and the methods used to test these means that studies are extremely test-device specific and it is impossible to adequately cover all single-use medical devices with all possible tests for different aspects of reprocessing and reuse. Therefore, the results of a particular study may not be externally generalisable/applicable to all single-use medical devices of a particular class or model. A lack of study reliability was a common limitation. The degree of study heterogeneity (medical devices, methods, outcomes) also limits the meaningfulness of results in a meta-analytic context. There are also difficulties in validating the study methods used to assess the safety and effectiveness of reuse.

There are implicit limitations with the evidence associated with laboratory studies using in-vivo and in-vitro experimental methods simulating contamination, cleaning, disinfection, sterilisation, reuse and potential cross-contamination. These artificial conditions and the surrogate endpoint results should be interpreted cautiously when comparing them to clinical situations.

There is some difficulty in defining a direct causal link between adverse patient outcomes and patient exposure to contaminated/malfunctioning reprocessed SUDs. The laboratory studies are disease orientated evidence (DOE) with surrogate endpoints rather than outcomes in patients (patient oriented evidence that matters-POEMs). There is an overall lack of literature adequately addressing patient outcomes evidence to support general clinical recommendations regarding the reuse of SUDs.

Gaps in knowledge

There are conflicting results from the studies reviewed and also in the general literature regarding the safety and effectiveness of SUD reuse, with some showing the safety and efficacy of some SUDs and others countering it. One of the few areas with support for reuse is electro-physiology catheters. Recommendations by the North American Society of Pacing and Electrophysiology (NASPE) are that in principle the reuse of electrophysiology catheters is safe and cost-effective provided there are stringent cleaning and sterilisation protocols in place and FDA standards are strictly adhered to (Lindsay et al. 2001).

Other areas such as hemodialyser reuse is extensive in countries such as the USA. Concerns have been raised regarding the safety of such practices with adverse events reported such as infection, toxicity associated with disinfection agents and pyrogenic reactions (Port et al. 2001). There is continuing controversy regarding reuse practices for hemodialysers. No greater mortality in patients was reported compared to no reuse in results from the US Renal Data System (USRDS) dialysis morbidity and mortality study, although greater mortality risk was apparent dependent upon the reuse agent (Port et al. 2001). A study by Feldman et al. (1999), a retrospective cohort study of hospitalisation rates in over 27,000 end-stage renal disease (ESRD) patients showed that free-standing facilities had greater hospitalisation rates than facilities not reprocessing, particularly those using peracetic/acetic acids or formaldehyde.

A reasonably well documented adverse event related to the reuse of medical devices is iatrogenic Creutzfeldt-Jakob disease (CJD). The first case was identified in the 1970s, but recently, of 267 CJD cases identified, in only seven of these cases was transmission related to contaminated reused medical devices, with most cases occurring after exposure to infected growth hormone extract and dura mater grafts (Brown et al. 2000). The data illustrate the infectivity of human tissue as all known cases relate to exposure to infected tissues of the brain, eyes, pituitary and dura mater and also long incubation periods. A variant of CJD known as vCJD was identified in the 1980s in the UK. Transmission occurred through exposure to contaminated bovine animals, and the disease manifested itself after a shorter incubation period (Rutala & Weber, 2001).

It is now better understood that CJD infection control requires unique disinfection and sterilisation methods given the unusual resistance of this prion disease to conventional decontamination methods (Rutala & Weber, 2001). The abnormal proteins associated with prion diseases are very resistant to all

conventional methods of decontamination, even extremely high temperatures (over 138°C), routinely used to sterilise surgical instruments does not inactivate CJD. Much of the work on the prevention of CJD cross-contamination from medical devices has relied upon laboratory prion inactivation studies. Data from these studies and from epidemiological data and infectivity data have assisted in developing guidelines for managing patients with or suspected of having CJD and critical and semi-critical medical devices (e.g., surgical devices) contaminated with high risk tissue (eye, brain, spinal cord) (Rutala & Weber, 2001). Published practical guidelines are now available – e.g., the Royal College of Ophthalmologists guidelines on CJD and Ophthalmology (Royal College of Ophthalmologists, 2002).

Research is progressing in establishing the efficacy of current and improved methods of decontamination in removing prion protein from medical devices. The only certain way to avoid the risks (not quantifiable at present) of reprocessed SUDs as being vectors of transmissible prions is to make all medical devices disposable.

In many other areas more research is needed with improved study methodology, as most studies are small non-randomised studies (case series) with inadequate statistical power to detect important clinical differences, inadequate follow-up and unreliable and possibly biased data. A significant proportion of the literature on the reuse of SUDs is in laboratory experimental settings and there is little evaluating the risks of cross-contamination and device failure in patients. Such events in patients are difficult to monitor and may go unreported (United States General Accounting Office, 2000).

There is only anecdotal evidence available on reuse and many areas require more research. This would be greatly assisted through the adoption of strict protocols on labeling and device tracking the number of times an item can be reprocessed, process controls, quality assurance, documentation, reprocessing methods chemicals, and equipment used for cleaning and sterilising (Dunn, 2002a). The FDA has set a precedent in terms of regulatory requirements for the practice of reprocessing and reusing SUDs.

There are ethical constraints in using patients in studies designed to determine the ‘risk’ associated with reusing SUDs, thereby limiting the overall evidence base. Despite the existence of guidelines and protocols governing the reuse of SUDs many items are still being reprocessed and reused without published data on the safety of these practices.

Conclusions

The evidence for the safety and effectiveness of reusing SUDs is indirect with the majority of studies set in laboratory contexts evaluating surrogate outcomes such as medical device integrity and contamination after reprocessing. Few studies involved outcomes directly related to patients. There is difficulty in adequately defining a direct causal link between patient exposure to contaminated or faulty medical devices and adverse patient outcomes due to a lack of data on cross-infection and loss of device functionality.

There are conflicting results from the studies reviewed. Some studies conclude that the reuse of SUDs is potentially safe and effective with strict reprocessing protocols and standards. Others do not recommend reprocessing and reuse because the evaluated devices were not clean or sterile and changes in device integrity were evident. These conflicting results were apparent for cardiovascular medical devices, anaesthesia devices, airways devices, and disposable plastic trocars. The reprocessing and reuse of sphincterotome devices was considered safe and effective with proper reprocessing standards. Studies investigating biopsy forceps consistently showed that reprocessing standards were not met as the devices were not clean nor sterile.

In the broader literature there is support for reuse of some devices under strict cleaning and sterilisation protocols such as electro-physiology catheters. An area of documented adverse events related to the reuse of medical devices is iatrogenic Creutzfeldt-Jakob disease (CJD), however few reported cases are related to contaminated medical devices. There is continuing controversy regarding hemodialyser reuse practices as this is extensive in countries such as the USA.

The degree of risk associated with reusing SUDs in patients has not been adequately documented due to a lack of data on the incidence of cross-infection and loss of device functionality. Adverse events are likely to be underreported due to a lack of surveillance and device tracking methods and the

possibility of legal liability issues. The literature reviewed is very device specific and the reliability of the results is limited because of the diversity of SUDs and methods used to evaluate reprocessing and reuse. It is recognised that many more areas require research. With the implementation of stricter regulatory environments, this will improve patient safety and enable improved monitoring of reuse practices but not necessarily improve cost-effectiveness.

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APPENDIX 1: LEVELS OF EVIDENCE

Table 10. Designations of levels of evidence*

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly-designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from descriptive studies e.g. case series, either post-test or pre-test/post-test designs

**Modified from NHMRC (2000)*

APPENDIX 2: SEARCH STRATEGY

Medline

- 1 disposable equipment/ (3286)
- 2 equipment reuse/ (1075)
- 3 1 and 2 (290)
- 4 single-use.mp. (483031)
- 5 disposable.mp. (4669)
- 6 reprocess\$.mp. (863)
- 7 reuse\$.mp. (2113)
- 8 (4 or 5) and (6 or 7) (466)
- 9 2 and (4 or 5) (309)
- 10 3 or 8 or 9 (703)
- 11 limit 10 to english (650)
- 12 limit 11 to yr=1997-2003 (362)
- 13 from 12 keep (selected references)

Embase

- 1 disposable equipment/ (943)
- 2 equipment reuse/ (3613)
- 3 1 and 2 (54)
- 4 single-use.mp. (333239)
- 5 disposable.mp. (2854)
- 6 reprocess\$.mp. (921)
- 7 reuse\$.mp. (2479)
- 8 (4 or 5) and (6 or 7) (331)
- 9 2 and (4 or 5) (168)
- 10 3 or 8 or 9 (471)
- 11 limit 10 to english (438)
- 12 limit 11 to yr=1997-2003 (283)
- 13 recycl\$.mp. (10724)
- 14 1 and 13 (58)
- 15 limit 14 to (yr=1997-2003 and english) (37)
- 16 15 or 12 (285)
- 17 from 17 keep (selected references)

Current Contents

- 1 single use
- 2 disposable
- 3 reprocess*
- 4 reuse* or reusing
- 5 #1 OR #2
- 6 #3 OR #4
- 7 #5 AND #6
- 8 sud OR suds
- 9 #6 AND #9
- 10 #9 NOT #7

Cinahl/Cochrane Controlled Trials Register

- 1 disposable equipment/ (566)
- 2 equipment reuse/ (434)
- 3 1 and 2 (174)
- 4 single-use.mp. (8596)
- 5 disposable.mp. (375)
- 6 reprocess\$.mp. (202)
- 7 reuse\$.mp. (263)
- 8 (4 or 5) and (6 or 7) (123)
- 9 2 and (4 or 5) (127)
- 10 3 or 8 or 9 (259)
- 11 limit 10 to english (255)
- 12 limit 11 to yr=1997-2003 (181)
- 13 recycl\$.mp. (172)
- 14 1 and 13 (14)
- 15 (4 or 5) and 13 (10)
- 16 14 or 15 (19)
- 17 16 not 10 (11)
- 18 limit 17 to (english and yr=1997-2003) (4)
- 19 12 or 18 (185)
- 20 from 19 keep (selected references)

APPENDIX 3: EXCLUDED STUDIES AND REASON FOR EXCLUSION

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Berenger, S. J., Ferguson, J. K., & Hughes, C. F. (2004). Re-use of single-use medical devices: how often does this still occur in Australia? (multiple letters). *Medical Journal of Australia*, 180, 46-47.

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Fagih, B., & Eisenberg, M. J. (1999). Reuse of angioplasty catheters and risk of Creutzfeldt-Jakob disease. *American Heart Journal*, 137, 1173-1178.

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Manns, B. J., Taub, K., Richardson, R. M. A., & Donaldson, C. (2002). To reuse or not to reuse? An economic evaluation of hemodialyzer reuse versus conventional single-use hemodialysis for chronic hemodialysis patients. *International Journal of Technology Assessment in Health Care*, 18, 81-93.

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Expert opinion/narrative review.

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Expert opinion/narrative review.

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Whitby, R. M., & Looke, D. F. (1997). "Single use only": obfuscation or the necessary attainment of zero risk? *Medical Journal of Australia*, 167, 519-520.

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