

WHY SINGLE-USE INSTRUMENTS?

HISTORICAL PERSPECTIVE AND NEED FOR CHANGE

A single-use medical device is intended for use on a single patient during a single medical procedure and then it must be discarded.

With the birth of new diseases, like BSE and CJD or increase of hepatitis, in the last decade, decontamination of medical devices has become a prominent issue. Increasing fears were realized in 1997, by which some 23 deaths from CJD had been recorded in Britain. By 2004, this number had arisen to 143. It is not known how many more people may be incubating the disease.

A study published in Sep 2004 by US FDA has confirmed that the infectious agents (prions) found in these diseases are very difficult to destroy by conventional methods even at elevated temperatures. This study was designed to examine the effects of the rigorous decontamination protocols, recommended by the World Health Organization (WHO), on various types of instruments. The most important conclusions were that such chemical procedures can cause (1) darkening of some instruments (2) damage carbon contents in metal and (3) corrode gold plating, welded and soldered joints.

Another recent research published in 'New Science' has revealed that even routine sterilization above 138C does not inactivate CJD. Infection may therefore spread through surgical instruments, endoscopes and laryngoscopes used previously in infected patients. A report published by the DWG identified that most of the sterilization sites assessed in the British hospitals were deficient in a number of key areas.

On a wider note, all kind of hospital-acquired infection (HAI) is a major concern for all healthcare providers. Recent estimate from the Public Account Committee, covering England have suggested that there are over 100,000 cases of HAI a year in England at a cost of Pounds 1 billion and causing 5,000 deaths. HAI can be caused by a variety of transmission routes, which includes inadequate reprocessing of reusable medical devices.

With the NHS spending more money each year for litigation settlement it's no wonder that there is currently a major government focus on cleaning up hospitals. Additionally, patients are placing increasing demands upon health care sector, much of which is driven by the media, to use more and more single-use devices.

A French public study undertaken in 1996 showed that:

- 92% would prefer to have single-use products used on them or their relatives.
- 60% were in fear of contracting disease by the use of reusable products.
- 62% were prepared to pay for single-use products.

Hospital infections are now the fourth leading cause of death in the United States, behind heart disease, cancer and strokes. (Reference: "The Hospital-Acquired Bloodstream Infections" Vol. 7 No.2)

With the statistics as serious as these it's no wonder that single-use medical devices are seen as a more effective measure for minimizing the risks involved.

As an alternative to disinfecting and sterilizing, more and more medical devices are being developed that are suitable for use only once. That means they have not touched any patient before and therefore pose no risk of cross-infection whatsoever.

Single-use products, after use, are contaminated hazardous waste that must be removed from hospitals as soon as possible and incinerated. In Britain guidance on disposal of clinical waste can be found in 'Safe Disposal' of clinical waste, issued by the Health Advisory Committee, HSC ISBN 07176 26927. The World Health Organization (WHO) has also recommended such instruments be incinerated.

The overall environmental burden of recycling single-use clinical waste, when compared with reusable, is unclear. In a report by Bell in 1998, it was noted that when considering the effect on the environment it should be remembered that the cleaning and sterilizing of reusable products and equipment have significant environmental implications and as such should not automatically be assumed 'environmentally more friendly'.

It may also be noted that after constant use, there are doubts about the quality of reusable instruments. Also key is the reliable monitoring and recording of the frequency of reprocessing and reuse for each individual medical device. Even if this problem is somehow brought under control, it will be at a huge capital investment, personnel costs and overheads.

If the reprocessing is contracted out, it may cost even more and also entail additional issues like, accountability, accessibility, repair/replacement, capacity, convenience, waiting time, transportation, audit trails and so on. Such a change may even result disruption, including task re-allocation or even redundancy of staff.

Converting to a single-use system may also entail an immediate budget increase due to bulk purchase, need for more storage space, specialist staff and incineration cost. However, the subsequent savings and convenience will effectively

offset these constraints. The cost effectiveness of eliminating the risk of fatal diseases might alone justify the use of single-use devices. Single-use may not be a viable option for all surgical procedures due to instrument availability, but should be adopted where such alternatives are available and effective.

Single use medical devices are often associated with convenience, improved reliability, time and cost saving. Because of their high volume, they often cost much less than the reusable. They are Ready-to-use, therefore, there is no waiting time, no cost for reprocessing, maintenance or post-operation tracking. Because they are new every time, there is no risk of infection. The attributes of single-use devices are multiple. These are the real key to success and peace of mind for the suppliers and users alike.

Reprocessing Single-use Medical Devices, A THREAT TO PATIENT SAFETY

Sterility:

Single-use medical devices are not designed with cleaning in mind. These must not be reprocessed and reused as stated in the MRHA document DB 2000 (04).

Functionality:

Reprocessing a single-use medical device is contrary to manufacturer's design may cause breakage of parts or impairment of performance.

Toxicity:

The residues left by surgical procedure or sterilization agents during reprocessing has the potential to cause toxic effects in patients.

Pyrogenicity:

Even if reprocessing kills bacteria, it will not necessarily destroy or remove the bacterial endotoxins on devices that were not designed to be re-cleaned.

Biocompatibility:

Reprocessing may alter the biocompatibility of a single use device, causing physical or chemical changes which may pose a threat to the patients.

Packaging:

The original manufacturer ensures that the packaging containing a single use device is protective and sufficient. Reprocessing may compromise this.

Legal Liability:

Anyone considering re-using these devices should be aware that this action will pass the legal liability from the manufacturer to the reprocessor.

Compensations:

Infections acquired in hospitals are an increasingly serious problem adding sizeable costs to the health service in financial claims on this behalf.

Informed consent:

If a single-use device is to be reused on any patient, that patient must be clearly informed about the risks involved and he must consciously agree to this form of treatment.