STERILISATION AND DISINFECTION GUIDE

1. STERILISATION

Sterilisation is a term describing the use of a physical or chemical procedure to destroy all microbiological life including bacterial spores. Major sterilising processes include dry heat sterilisation, steam sterilisation under pressure, low temperature hydrogen peroxide plasma sterilisation, automated peracetic acid systems and ethylene oxide gas[1,2.] A number of chemical germicides are capable of achieving sterilisation if used for prolonged periods. To achieve sterilisation with aldehyde based products, depending on use temperature, a contact time exceeding three hours may be required. At present modern flexible endoscopes cannot be regularly sterilised, either because processes such as heat and steam are incompatible with the materials of which they are composed or because processes such as ethylene oxide and extremely prolonged chemical immersion are impractical and unlikely to achieve full sterilisation for the reasons subsequently outlined. A few newer model endoscopes are proposed as capable of undergoing low temperature gas plasma sterilisation but the long term effect on materials from repeated use of this process is not yet clear.

2. DISINFECTION

Disinfection is different from sterilisation. Disinfection is a process that only removes or kills organisms that are regarded likely to cause disease. Many organisms are relatively resistant to disinfection. In general they are regarded as low virulence organisms, e.g. bacterial spores. Other forms of microbial structures designed to allow survival in hostile environments, e.g. protozoal cysts, are also resistant.

Any item that comes into contact with sterile body sites needs to be sterile. Sterilisation is also preferable for instruments that come in contact with an intact mucous membrane, but unfortunately because of the structure of many instruments (including endoscopes), this is not achievable either because the instrument cannot withstand heat or the impracticable logistics of using other sterilisation processes (e.g. gas sterilisation).

Disinfection can be achieved by a number of means that include heat and chemicals. The cleaning process itself is a very efficient means of achieving disinfection. Cleaning removes or destroys more organisms than a chemical disinfectant is likely to do over a similar period of time (e.g. a 5 minute contact time). Organic material binds and inactivates many chemical disinfectants. Some disinfectants such as glutaraldehyde and alcohol fix protein. Thus chemical disinfectants may create a physical barrier of denatured protein that can protect organisms coated by organic material. Obviously no agent can be effective against microorganisms it cannot reach. An advantage of heat as a disinfecting agent is that it is conducted and is able to penetrate better than chemicals. The action of heat will also be compromised by inadequate cleaning, but to a lesser extent than with chemical disinfectants. With high levels of wet heat and pressure

(autoclaving) sterilisation is achieved. When heat is used at lower temperatures, e.g. boiling water or pasteurisation (70°C for 100 minutes - 90°C for 1 minute), heat is a very effective disinfectant.

For instruments that come in contact with mucosal surfaces, a high level disinfectant is required. Disinfecting agents need to kill all forms of bacteria (gram positive, gram negative and mycobacteria), viruses (both the more sensitive lipid coated viruses such as HIV and relatively resistant viruses such as the polio virus), fungi (e.g. Candida) and protozoa (e.g. Giardia). High level disinfectants are able to kill the more resistant forms of microbial life such as bacterial spores and cysts but only with prolonged contact times (usually over 3 hours).

No sterilising or disinfection agent works instantaneously. They all require sufficient contact times. The ability to achieve complete killing of microorganisms is dependent on a number of factors.

1. **Initial number of organisms present**.

This is a critical factor as there is a log kill with time. Therefore the higher the number of organisms present, the longer it will take to achieve a complete kill. This is a further reason why cleaning is a critical step in any cleaning disinfection protocol. A log five reduction or more in the number of organisms present can certainly be achieved by scrupulous cleaning.

2. **Temperature**

In general the higher the temperature, the quicker the disinfecting agent will destroy organisms. This concept is used to allow rapid cycle times in AFER's, including machines which use glutaraldehyde and those which use peracetic acid. For manual reprocessing, the use temperature is provided on the product label. The use temperature for glycolated glutaraldehyde (Aidal Plus) is 25 degrees or 35 degrees whilst OPA is used at 20 degrees. Biocidal activity is likely to be reduced at temperatures lower than those recommended for use and recommended soaking times will thus be inaccurate.

3. Concentration

Concentration of a chemical disinfectant is critical. In general the lower the concentration of the agent, the longer it will take to kill the same number of organisms. It is particularly important to ensure that disinfectants do not become diluted with excess water remaining on endoscopes after rinsing. Concentration of an agent (e.g. 2% glutaraldehyde) may be more than halved with repeated use and the activity of the disinfection process significantly compromised. The chemical concentration should be checked using test strips at the beginning of each day.

4. Contact time

There is no specific soaking time that will guarantee that all agents present are killed by chemical disinfectants. It is dependent on the number of organisms present, the presence of inactivating compounds (e.g. organic materials), the pH, the temperature, the concentration of a disinfectant and the relative resistance (and therefore kill rate) of the organism involved. Recommendations given are for an adequately cleaned endoscope. If cleaning is compromised, even prolonged contact time (in excess of 60 minutes) is unlikely to kill pathogenic organisms present on or in the endoscope. It has been shown that ten separate full disinfection cycles failed to kill *Mycobacterium tuberculosis* present in an inadequately cleaned bronchoscope[3].

3. BIOCIDES FOR ENDOSCOPE REPROCESSING

Agents, which can achieve high level disinfection, include 2% glutaraldehyde, 0.55% *ortho*-phthalaldehyde (OPA), peracetic acid, high concentrations of hydrogen peroxide and some chlorine releasing agents. In general peracetic acid and high concentrations of hydrogen peroxide can only be used in automated processors which prevent staff exposure. Glutaraldehyde and OPA can be used in either manual processing or in automated processors. Ethylene oxide achieves sterilisation with prolonged contact time. However, it must be recognised that gas sterilisation with ethylene oxide is subject to the same limitations as liquid chemical disinfectants. Gas sterilisation cannot be achieved in inadequately cleaned instruments.

Other chemicals such as quaternary ammonia compounds (e.g. Cetrimide) are only low level disinfectants and are inactive against many bacteria (pseudomonas, mycobacteria). They have little or no activity against viruses. Alcohol and iodine, while more effective than quaternary ammonia compounds, do not kill some forms of micro-organisms and are therefore not regarded as high level disinfectants.

It is customary to state that endoscopes undergo high level disinfection[4]. In practical terms, however, endoscopes cannot always be rendered free of all bacterial contamination by standard cleaning and disinfection processes.

Endoscopes subjected to the full cleaning and disinfection protocols advocated in this monograph and then having their channels filled with culture medium and stored in sterile bags, may still grow bacteria after several days. This is particularly so in older instruments where irregularities at junctions, minor cracking or splitting of the surface layers of the internal channels may allow protection of organisms[5,6,7]. The realistic aim, therefore, of any reprocessing protocol is to have an endoscope, which will not transmit pathogens from one patient to the next, nor hospital environmental contaminants from the endoscope or accessories to the patient. In addition, it is important to recognise there are a wide variety of other factors which influence whether or not significant clinical infection will occur when endoscopic procedures are undertaken. It is critical to have an appreciation of all the factors involved.

4. STERILISATION VS HIGH LEVEL DISINFECTION: PRACTICAL ASPECTS

Sterility is a simple theoretical concept. Demonstrating its existence in practice is rather more difficult. It is impossible to test each item; batch testing of large production lines provides little assurance. In practice, the concept of Safety Assurance Levels (SAL) is used[8]. A selected microorganism (usually a bacterial spore) is tested under fixed conditions in a sterilising process and the chance of live organisms remaining extrapolated from the kill graph. The usual convention is that a device labelled as sterile has an SAL of 10^{-6} [9,10]. This means that there is a less than 1 in 1 million chance that live organisms remain on the device. Over time there has been a progressive demand for higher Safety Assurance Levels to apply to devices labelled "sterile". Indeed, there is now a push to increase this SAL to 10^{-8}. This is despite the fact that there is no evidence of worse clinical outcomes when devices with SAL's of 10^{-3} are compared with SAL's of 10^{-6}, let alone 10^{-8}! [11,12]

There are increasing pressures demanding that endoscopes should be "sterile". At least one State in America is considering legislation to this effect. There is no evidence anywhere that patients have suffered infections with organisms which would be eliminated by a sterilising process but not by a high level disinfection process.

The facts are:-

1 No currently available technique of reprocessing flexible endoscopes can guarantee sterility of every endoscope on every occasion.
2 Passing "laws" or publishing standards which are simply impossible to comply with in practice is deceptive to the public, exposes the reprocessor to possible litigation and offers a false sense of security to the ill-informed.
3 Safety in endoscope reprocessing is the sum of its component parts. No sterilising process can be effective if the instrument has not been meticulously cleaned or is mechanically defective. The sterilising process itself will only work if all parts of the endoscope are exposed to the chemical for an appropriate time and at an appropriate temperature, and rinsed with sterile water. It is truly farcical to suggest that a sterilising

process with no flow alarms, defective self-sterilising cycle, and using unsterile, possibly contaminated rinse water is guaranteed to achieve a better clinical outcome than a properly applied high level disinfection process which does not suffer the above defects.

American and British guidelines on bronchoscopy continue to state that high level disinfection is the recommended procedure with no comments regarding full sterilization. Bronchoscopy like endoscopy is a procedure which does not breach into a body cavity. Note that because biopsy forceps do breach the mucosa they should be sterilized or discarded if disposable. [13,14]

Recent Pseudomonas cross infection from flexible bronchoscopes in two separate reports was shown to be due to faulty bronchoscope design. It was not due to the use of high level disinfection rather than sterilisation[15,16]. Some studies report water filtration systems are not able to reliably provide bacteria-free water.[17] In this study no mycobacterial contamination of bronchoscopes was observed but the water sampled over a period of months from a filter in an automated flexible endoscope reprocessor (AFER) repeatedly grew mycobacteria. From this aspect alone, the impracticalities of attempting to perform a fully sterile procedure are demonstrated.