Appendix:

Batch Control Identification (BCI)

As a quality assurance or risk reduction measure, dental practices should use a system for critical packages of equipment, i.e. critical instruments used in surgical procedures. This requirement arises from AS/NZS 4815 which states batch control numbers should be in place to link steriliser cycle batch information of a critical item that has been sterilised to the patient.

Batch Control Identification (BCI) links a pack of surgical instruments used on a patient to a particular sterilising cycle and thereby allowing dental practitioners to demonstrate critical dental instruments used on the patient have been through a particular steriliser cycle with verifiable performance data. This does not apply to semi-critical items used in routine dentistry. Thus, in office-based general dental practice the use of BCI would be limited.

A batch code comprises a simple sequence of numbers, such as those produced from a labelling gun, or can be combinations of a number sequence with codes for the date and the steam steriliser number (if the practice has several steam sterilisers). As described in AS 4815, the BCI includes the steriliser identification number or code (if there is more than one steriliser within the facility), the date of sterilisation, and the cycle or load number.

Batch information can be recorded on packs prior to steam sterilising using non-soluble permanent marker ink, or by using adhesive labels applied with a labelling gun, provided the inks and adhesives used can tolerate steam sterilising.

Several segmented (piggyback) adhesive label systems are available, where one part of the label is peeled off the pack when setting up for the procedure, and placed directly under the day's entry on the patient's hard copy chart. Systems exist which include batch identification printed in barcodes which can be scanned for entry into electronic patient records.

At the time of the critical procedure, as instruments are removed from their packages, the empty packages should not be immediately placed into the waste, but rather put to one side in a clean zone of the operatory. Batch number information can later be recorded into the patient's treatment records by the clinician responsible, as part of writing up the procedure notes.

The ADA supports BCI for instruments that enter, or are capable of entering, tissue that is normally sterile. This protocol uses batch control numbers to link an item's steriliser cycle batch information to the patient record entry for a specific procedure. The Spaulding instrument classification BCI aligns with the possibility that instruments, if incorrectly sterilised, may introduce pathogens into critical sites. BCI links the surgical instruments used on a patient to a particular sterilising cycle and thereby allows dental practitioners to demonstrate that critical dental instruments used on a patient have been through a particular steriliser cycle with verifiable performance data.

It allows proper examination of instances where instrument sterilising processes and practices are in question and is worthwhile in terms of public good. BCI has been widely used in the dental profession for some years and is a well-established protocol.

BCI is clearly designated as a mandatory requirement in AS/NZS 4815 and AS/NZS 4187. Both require pouches or packages with individual instruments or instrument sets to have BCI recording:

1. Steriliser identification number or code
   (if there is more than one steriliser within the office-based health care facility)
2. Date of sterilisation
3. Cycle or load number
4. The manufacturer's batch/lot number of any commercially prepared implantable items

As stipulated in AS/NZS 4815, batch numbers link the steriliser cycle batch information for a critical item that has been sterilised back to the appointment the patient attended. In addition to surgical instruments, batch numbers should be used for sterile surgical drapes.

Batch numbers and date information can be placed on packages by hand using an indelible pen, using a self-inking stamp, or by using adhesive labels from a labelling gun.

It is important the inks used do not run or become unreadable during steam sterilisation. If a stamp is being used, the same stamp used to mark the date and steriliser cycle information can also be used to make a stamped entry into the steam steriliser record book for the relevant load.

The steriliser cycle record book is an important legal written record, and will be a key piece of evidence if claims are made about inadequate sterilising practices.

This is used together with the signed printouts to record the key characteristics of each cycle. This record book must be filled in when the cycle is loaded, with the date, cycle number, load type and cycle programme. It is also recommended that the identification of the loading operator be included (e.g. their full name, initials or operator code). This task should be completed before the cycle start button is pushed. At the end of the cycle, the unloading operator fills in the information for physical parameters (e.g. based on the printout), and the status of the chemical indicators are okay, before signing off the load is suitable for use.