PCSA Guidelines on Decontamination of Reusable Surgical Instruments

For the majority of GP's in Ireland, disposable surgical instruments are the safest, most convenient and cost effective method of ensuring safe instruments for surgery.

However, for practices who do high volume and/or more complex surgical procedures and who do not rely exclusively on disposable instruments or instruments sterilized by a hospital CSSD Department, the following guidelines are recommended:

1. After use, the operator will remove any heavy contamination from the instruments at the surgical table with a solution of Chlorhexidine 0.015% and Cetrimide 0.15% (''Sterets, Tisept'') or another suitable solution and then soak the instruments in Gigasonic disinfectant 3% solution (120ml in 3.8 litres of water) or another suitable solution. Fresh solution should be made up for each surgical session.

For Practices **without** a washer/disinfector machine at present, see points 2, 4, and 5 below:

2. After soaking in the disinfectant for at least five minutes, the nurse or healthcare assistant will remove the instruments in a separate disinfection room and put them through a cycle of an ultrasonic cleanser which is CE approved with Biosonic (one sachet in four litres of water) or another suitable solution as recommended by the manufacture of the ultrasound cleanser.

3. He/she will then remove the instruments, inspect them and, if necessary, scrub them with a brush at the basin while they are healed under water to avoid splashing, being particularly careful to clean the inside of scissors and forceps. He/she will wear protective glasses, a nose and mouth mask, an apron and gloves when cleaning the instruments.

4. All surfaces will be sprayed with Euro Sept Max Surface or another suitable solution after scrubbing the instruments and the solution will be allowed to soak into the surfaces, including the taps and handles. The scrubbing brush should be soaked in Gigasonic disinfectant 3% solution (120ml in 3.8 litres of water) or another suitable solution for five minutes.

5. It should be noted that manual cleaning is the least preferred method of reusable surgical instrument decontamination and should be discouraged due to the high risk of percutaneous injury and splashing with infectious material during cleaning (HSE 2012).Best practice requires the use of a validated washer disinfector to clean and disinfect instruments prior to wrapping for sterilization.

6. Ideally all practices should eventually have a washer-disinfector which is CE approved as this can be used instead of points 2, 3, 4 and 5 above.

7. After the instruments have been cleaned, they will then be packed in sterilizing pouches. Soaking, ultrasound cleaning (or washer/disinfector), scrubbing and bagging should be carried out in a unidirectional flow in the decontamination room. The filled sealed pouches are then put through a cycle of the class B autoclave. A printout of the cycle log will be kept in the decontamination ledger or downloaded onto a decontamination file on the PC.

8 The bags are then removed from the autoclave and each pack will be stamped showing the time and date of sterilization, which will correspond with the printout for that particular cycle. Packs will be re sterilized if not used within six months.

9. The batch number of each pack will be entered into the patient file (eg: time and date code: 1125/27/10/14 = 11:25am on 27/10/14).

10. - Once a week the ultrasonic cleanser will be tested with silver foil.
    - Once a week the dishwasher-disinfector will be inspected for faults.
    - Once a week the autoclave will be checked with a Bowie Dick test.

11. The ultrasonic cleanser or the dishwasher-disinfector and the class B autoclave will be serviced by a qualified engineer annually and the service report will be kept with the decontamination ledger.

12. All doctors, nurses and healthcare assistants must be vaccinated against Hepatitis B and will receive training and supervision on decontamination from the doctor in charge of the surgery. All practices should have an infection control policy. The medical indemnity company for the practice should be informed that the practice decontaminates their reusable surgical instruments.

These guidelines were endorsed by the PCSA membership at our AGM on 26/9/15.
These guidelines are based on the HSE document “Infection prevention and control for primary care in Ireland” - Chapter 8 (2013) which is summarized below:

Infection prevention and control for primary care in Ireland - Chapter 8

The Quality and Patient Safety Directorate have identified the need to develop Standards and Recommended Practices for decontamination of RIMD - General Practice, this piece of work will be incorporated into the Directorate plan.
The options from which practices that use sterile medical devices must choose are: -
1. The use of sterile single use devices, which will obviate the need for decontamination.
2. Have reusable devices sterilised by a certified Sterile Services Department (SSD).
3. Decontamination of devices in the practice .

1. Single use devices
A single use device (SUD) is a medical device that is intended to be used on an individual patient during a single procedure and then discarded. Medical devices that are for single use must be clearly labelled with the words "do not reuse" or display the do not reuse symbol

Single use devices must not be decontaminated and reused as this can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risks.
NB Single patient use devices
A medical device that is intended for single-patient use means that the device may be used for more than one episode of use on one patient only e.g., nebuliser.

2. Reusable devices sterilised by a certified Sterile Service Department (SSD)
If the users of sterile invasive medical devices opt to have reusable devices sterilised by a certified Sterile Services Department (SSD) in either a public/private hospital this SSD is then termed a "system and procedure pack manufacturer" and the requirements of the regulations as laid down by the Irish Medicines Board (2007) must be met and the devices must comply with all the relevant essential requirements.

3. Decontamination of devices in the practice.
The reprocessing of reusable invasive medical devices should comply with the recommendations set out in the following: -
Code of practice for decontamination of RIMD (HSE 2007).
Decontamination of Reusable Medical Equipment

Irish Medicines Board (IMB) (2005) Guide: Manufacture of Medical Devices within Healthcare Institutions.
Safe and Effective Use of Bench-top Steam Sterilisers, IMB SN2009 (04).
Irish Medicines Board (IMB): Cleaning and decontamination of reusable medical devices IMB safety notice; SN2010 (11).

The following must be in place where decontamination of reusable medical devices takes place: -

- Documented robust and comprehensive policies and procedures to ensure that decontamination processes are undertaken in a controlled manner to protect the health and safety of patients and staff.
- Manual cleaning of devices is restricted to those items deemed incompatible with automated processes.
- Equipment used to decontaminate devices must be fit for purpose, validated and tested in accordance with current recommendations.
- Organisations should have systems in place to trace instrument sets through decontamination processes and to the patient.
- A documented training scheme must be in operation with individual training records for all personnel, including management involved in decontamination activities.

It is critical that decontamination of the medical device in question should be carried out in accordance with the device manufacturer's instructions. If there is no reprocessing information provided with the device, then the manufacturer should be contacted for guidance.

Users and potential purchasers of bench top vacuum steam sterilizers should be aware the benchtop sterilizer should comply with the requirements of EN 13060 B cycle vacuum sterilizers are recommended.

Please note that so-called 'prion cycle' alone will not inactivate prions 57 .
Suitability of decontamination facilities

Decontamination facilities should be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination of clean and disinfected RIMD.

- The decontamination area must not be used for any other purpose.
- The decontamination area must not be part of any patient treatment area.
- The decontamination area should contain dedicated manual cleaning equipment and accessories for specified RIMD that cannot be cleaned in an automated cleaning process.
- The thermal washer disinfector should comply with the Standard requirements of EN 15883
- The decontamination area must contain separate sinks for washing and rinsing 39 .

(Interested readers may wish to refer to Appendix 7 where the rationale for these recommendations is outlined in greater detail)

Decontamination of medical equipment
Decontamination of reusable invasive medical devices (RIMDs)
Decontamination is the combination of processes (including cleaning, disinfection and sterilisation) used to render Reusable Invasive Medical Devices (RIMDs) safe for handling by staff and for use on patients.
Cleaning is the process that physically removes soiling, including large numbers of microorganisms and the organic material on which they grow. This is usually carried out using neutral detergent and warm water. Detergent wipes may be

used provided they have not dried out.

Disinfection describes a process that eliminates many or all-pathogenic microorganisms from inanimate objects, with the exception of bacterial spores, e.g. disinfection of environmental surface with a sodium hypochlorite solution. The use of disinfectant wipes is not advised.

Sterilisation refers to a physical or chemical process that completely kills or destroys all forms of viable microorganisms from an object, including spores. This is usually carried out in an autoclave.

Medical device: The term medical device covers a very wide range of products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness, disease or handicap. The range of products covered by the term includes items such as bandages, surgical instruments, syringes and blood glucose monitors, etc. For a device to be regarded as a medical device, it must have a medical purpose intended .
Medical devices are classified depending on their perceived risk. Instruments and equipment should be cleaned and reprocessed according to the level of risk associated with their intended use. The Spalding classification of infection risk is outlined in the "Code of practice for decontamination of RIMD (HSE 2007)"
Decontamination risk assessment

A risk assessment needs to be carried out for each piece of equipment.
This should include: -
How the item will be used
Which patient it will be used on
The potential risk of this equipment acting as a reservoir or vector of Infection

This risk assessment will determine what level of decontamination is required. In general, it is difficult to achieve adequate decontamination in a General Practice setting where the infection risk is classified as critical or semi-critical. For this reason the use of single use/disposable equipment is preferable. Decontamination where the risk is non-critical can generally be achieved by cleaning (detergent wipes or solution of detergent and warm water). Decontamination should always be carried out in accordance with the equipment manufacturer's instructions.