

Standards for the decontamination of reusable podiatry instruments in primary care



**The Society of
Chiropodists and Podiatrists**

Chapter 8



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INTRODUCTION

1. Patients have the right to expect to be treated in a safe, clean environment and to know that any reusable instrument has been decontaminated according to the level of clinical risk encountered. The prevention and control of healthcare acquired infections must be a high priority for all members, and should be embedded into everyday practice, for everyone working within the clinical environment.
2. These guidelines are to help achieve an appropriate standard for the decontamination of reusable podiatry instruments that come into direct contact with the skin. Members however, should undertake an independent risk assessment to satisfy themselves that their practice is legal, safe and effective. Compliance with these guidelines should help to achieve this.
3. The guidelines are not intended for members undertaking podiatric surgery. It is expected that all podiatric surgeons will use instruments that have been through an accredited central sterilisation unit, when performing invasive procedures.

DECONTAMINATION

4. Decontamination is the combination of processes which includes cleaning, disinfection and sterilization to render a reusable item safe for further use. Separate guidance is available on second-hand equipment and items sent for repair. There should be systems in place to ensure:
 - Reusable medical devices are decontaminated in accordance with manufacturer's instructions and current guidelines;
 - Medical devices are tracked through the decontamination process in order to ensure that it has been carried out effectively; and
 - Where members intend to undertake NHS contracts, to ensure that it is possible to identify the patient or patients on whom the medical device has been used (this is a requirement of the Health Act 2006: Code of Practice for the Prevention and Control of Health Care Associated Infections).
5. Members are encouraged to display the Society poster outlining the decontamination process within the area that they undertake the decontamination of reusable instruments (see Appendix I).



ARRANGEMENTS SHOULD BE FIT FOR PURPOSE

6. Ideally the reprocessing of reusable podiatry instruments should be performed in dedicated facilities and outside the immediate patient environment. Where this is not practical, then decontamination may be undertaken within the clinic. If, however, you are moving premises or undertaking a major refurbishment of your current practice, you should consider moving decontamination outside the immediate clinical area.

7. The layout of the decontamination area should reflect the progression of instruments from dirty instruments, to cleaned instruments and then sterilized instruments. Equipment used to decontaminate podiatry instruments should be fit for purpose and whenever possible validated. There should be a dedicated clean sink for hand washing. Where manual cleaning is performed, see below, there should ideally be two sinks – a 'dirty sink' for the washing of used instruments, and a 'clean sink' for rinsing of washed instruments. Where a separate 'clean sink' is not practical in the short-term a separate bowl may be used.

CLEANING OF INSTRUMENTS

8. Effective cleaning of instruments is an essential prerequisite before sterilization. The principal methods currently available for cleaning reusable podiatry instruments include:

- Cleaning, using an automated washer-disinfector;
- Manual, combined with ultrasonic cleaner; or
- Manual cleaning

9. The Society recommends, wherever possible, that automated methods such as washer disinfector or ultrasonic cleaners are used. Whichever method is adopted, it is essential that it is seen as a prerequisite to sterilisation and that the instruments are checked to ensure that they are free of debris and visible contaminants before being sterilised.

Cleaning using a washer disinfector

10. Using a washer-disinfector is the preferred method for cleaning podiatric instruments because it offers the best option for control and validation of cleaning. Washer disinfectors are less labour intensive and have less health and safety implications. They are, however, more expensive and require additional space and so may not be possible in all situations.

Ultrasonic Cleaners

11. Ultrasonic cleaners may be used as an adjunct to manual cleaning. It is, however, important that the correct cleaning fluid is used; in accordance with manufacturers instruction, and that the cleaner has a cover to minimise the risk of aerosol contamination of the atmosphere. The cleaner should be emptied at the end of the day, or sooner if it appears to be heavily contaminated. Good maintenance is essential. For safety reasons, ultrasonic cleaners should not be used within the clinical environment.



Manual Cleaning

12. Manual cleaning governed by a separate protocol (see appendix II). Manual cleaning is acceptable but is difficult to validate and so should not be used for instruments intended for invasive procedures.

Rinsing, inspection and care of instruments

13. Instruments cleaned in an ultrasonic cleaner or by hand should be rinsed thoroughly to remove residual debris and detergent, in a dedicated sink or bowl. This step may be omitted if a washer disinfectant is used.

14. Whichever cleaning method is used, all instruments should be checked after cleaning, to ensure that they are clean, functional and in good condition. If there is any residual debris remaining on the instruments following cleaning, the instruments must undergo another cycle of cleaning. Occasional use of a lubricant may be required for moving parts; a non oil based lubricant should be used to avoid interfering with the sterilisation process.

15. Where the instruments are to be sterilized in a:

- vacuum autoclave, they should be dried using a disposable non-linting cloth before being wrapped, if it is intended to sterilize them wrapped; or
- non-vacuum autoclave, or unwrapped in a vacuum autoclave, they should be sterilised as soon as possible after cleaning to avoid air-drying, which can result in corrosion and microbial growth.

STERILIZATION

16. The Society accepts the use of bench top autoclaves for the sterilisation of podiatry instruments. The autoclave should be:

- Used in accordance with the manufacturer's instructions and any safety requirements; and
- Installed, commissioned, validated and maintained appropriately in compliance with the manufacturer's instructions.

17. All steam sterilizers are subject to the Pressure Systems Safety Regulations 2000 and must be examined periodically by a Competent Person (Pressure Vessels).

Printer

18. It is not a legal requirement to have a printer or data logger attached to the autoclave; however, it is advisable as this can assist with the tracking of instruments and fulfil your daily testing requirements. For this the Society recommends that all members, when purchasing a new autoclave, select a model that has a data logger or printer attached.



Recommendations for the use of benchtop sterilizers

Temperature

19. Sterilization should be performed at the highest temperature compatible with the instruments in the load. For podiatry instruments and equipment, the Society recommends that autoclaves should reach a temperature of 134-137°C for three minutes. This is the standard that it expects all members to conform to by 31 December 2010. Until then, the Society will also accept the following time-temperature relationships: 126°C for 10 minutes and 121°C for 15 minutes.

Water

20. Change the water in the reservoir of benchtop steam sterilizers regularly – at least daily – using distilled water. Where invasive procedures such as nail surgery, wound management, or blunt dissection are undertaken, members must use freshly prepared distilled or reverse osmosis (RO) water, or sterile water for irrigation.

21. Used water when emptied from the reservoir should be disposed of via the dirty sink, so as not to contaminate the clean sink.

Loading of instruments

22. Where instruments have a lumen a vacuum autoclave is necessary. A vacuum autoclave also permits the sterilization of wrapped instruments, this can be advantageous in some circumstance, but is not necessary where wrapped or lumen items are not being sterilised.

23. Instruments in a non vacuum autoclave must be loaded in such a manner to allow sufficient circulation of steam and therefore adequate sterilization (see Appendix III).

Testing

Commissioning

24. A new autoclave must never be used straight from the box without being first being commissioned. All autoclaves should be installed by the supplier or manufacturer, to ensure that it is safe to operate and that it functions within predetermined parameters. This commissioning must be fully recorded in the log book.

Validation and Maintenance of benchtop sterilizers

25. In addition to commissioning all autoclaves need to be validated annually and maintained according to the manufacturer's instructions by a test person qualified to maintain benchtop sterilizers.

26. Each autoclave should have a logbook (file) in which details of the maintenance, validation, faults, modification and routine testing are recorded. The logbook should be kept up-to-date and kept in close proximity to the benchtop steriliser.



User testing

27. Testing is an integral part of ensuring the benchtop sterilizer consistently performs to the operating parameters set during the machine's commissioning and maintenance. Failure to comply with the regular testing of the autoclave could compromise safety, may have legal implications, as well as possible implications for your professional indemnity and pressure vessel insurance.

28. Daily and weekly checks are required and observation recorded on a form such as that suggested in Appendix IV, which should be stored with the autoclave logbook. Each day checks must be performed to ensure that the benchtop steriliser holds the target sterilization temperature and pressure for the specified time, that the chamber and shelves are clean and free of debris and that the rubber door seal is clean, using a damp non-linting cloth.

29. The test can be performed with a load in the chamber, but should be conducted with the same or similar load every time. If the autoclave fails to hold any of the target sterilization temperature and pressure for the specified time, repeat the test and, if it fails again, call the maintenance contractor.

30. For vacuum benchtop sterilizers, it is necessary to undertake a weekly air pressure leak test. It is therefore advisable that any vacuum autoclave has an automated air pressure leak test. Additionally it is necessary to undertake a daily Bowie-Dick-type test pack (conforming to BS EN 867:2001), so as to ensure adequate steam penetration.

Pressure vessel insurance

31. Steam sterilizers of any type are legally required to have specific pressure vessel insurance.

STORAGE AND USE OF DECONTAMINATED INSTRUMENTS

32. Instruments sterilised in a non-vacuum autoclave, intended for nail surgery and wound management should be used as soon as practicably possible, after allowing time for the instruments to cool down. Instruments for other procedures must be used on the same day that they were sterilized. Prior to use they should be stored in a clean dry disinfected air tight container and not covered with a blue paper towel.

33. Instruments that have been sterilised wrapped using a vacuum benchtop should be used on the stock rotation principle of 'first in – first out'. There is no specified shelf life for sterile wrapped instruments as long as the package remains clean, dry and intact.

TRAINING AND SAFETY

34. It is important that anyone who is undertaking the decontamination of instruments within podiatry as part of their continuing professional development keeps up-to-date with an



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acceptable standard for decontamination. Also that they read the manufacturer's instructions for any equipment and also safety information sheets for any chemicals that they may use.

35. It is important to undertake COSHH assessments on any chemicals used and to adhere at all times to the manufacturer's safety recommendations. Suitable personal protective equipment, eye and mouth protection, gloves and waterproof apron should be worn at all times when decontaminating instruments.

36. Schools of podiatry have been asked to give consideration to the necessity of teaching high quality local decontamination protocols to students who are, in the main, destined for primary care. For ease of reference a checklist of the competencies for a person undertaking the decontamination of instruments is provided in Appendix V, these competencies are equally applicable to qualified members as well as podiatry students.

LIST OF APPENDICES

- A Overview of decontamination process (wall poster)
- B Manual cleaning protocol
- C Loading of instruments for sterilisation in a non-vacuum autoclave
- D User testing record forms
- E List of competences
- F Instrument Traceability Systems



Appendix A

Decontamination Process





Appendix B

Manual Cleaning of Instruments

Immersion Method

Check that it is safe to immerse the device.

Not for electrical equipment

1. Fill the clean sink or receptacle with water below 35°C. Wearing protective clothing, dismantle or open the instrument to be cleaned (where appropriate) and remove gross soiling by brushing, wiping, agitating and irrigating the item while it is submerged, taking care to ensure it remains under the surface of the water at all times to prevent the creation of aerosols. Remove the item, drain it and then rinse it by submerging, and agitating, it in clean water in the second sink.
2. Clean the first sink or receptacle and refill with water and detergent at the dilution, and if possible at the temperature specified by the detergent manufacturer and/or local documented policy/procedures. It is important to use detergents as close as possible to the temperature recommended for maximum efficiency. Enzymic detergents can be inactivated if the solution is too hot.
3. Fully immerse the item in the solution to displace trapped air and ensure contact with all surfaces of the item being cleaned.
4. Brush, wipe, agitate, irrigate, the item to dislodge and remove all remaining visible soil, again taking care to ensure the item remains under the surface of the water at all times to prevent the creation of aerosols.
5. Remove the item from the sink and drain any excess detergent before rinsing it thoroughly by submersion and agitation in clean water in the second sink.
6. Remove and drain the item ensuring it is not re-contaminated.
7. Dry using the preferred method.
8. Complete any necessary documentation to record the item being processed and the method and solutions employed.

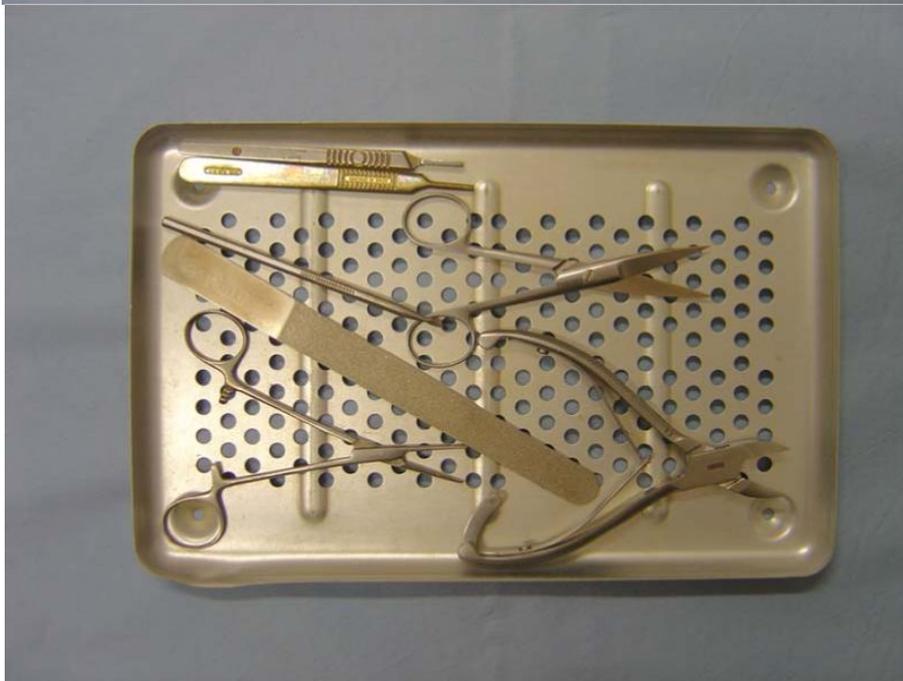
If either the cleaning solution or the rinse water becomes obviously soiled or contaminated, it should be changed and the process repeated.

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Appendix C

Photographs showing how to, and how not to load a tray of instruments for sterilisation in a non-vacuum autoclave.





Appendix D

User Testing of Benchtop Sterilizers

(non-vacuum autoclave)

Record Sheet

Daily Tests

Date:						
Cycle number:						
Max Holding Temperature:						
Min holding Temperature:						
Pressure during holding temp:						
Total time at holding temp:						
Testers Initials:						
CHECKED CHAMBER						
CHECKED DOOR SEAL						
CHANGE WATER						

Weekly tests

		Comments	Testers Initials
Door seal secure	Yes/No		
Door safety device functioning correctly	Yes/No		



Appendix E

A checklist of competencies for persons undertaking the decontamination of reusable podiatry instruments

1. To understand the importance of proper decontamination of reusable podiatry instruments to reduce the risks of cross infection.
2. To be aware of the need to keep dirty and clean instruments separate and of the importance of maintaining a process that achieves a 'one-way' trip from the dirty to clean area, that avoids dirty water being splashed onto sterilised instruments, or onto work surfaces on which cleaned and sterilised instruments will be laid.
3. To be able to locate and understand the COSHH assessment forms for chemicals used in the decontamination of instruments.
4. To identify appropriate protective equipment/clothing and to understand when to use it when decontaminating instruments.
5. To know what actions to take should a needlestick injury occur and why urgent action is necessary.
6. To be trained in the use of an eye wash kit in the event of a splash contaminating an eye.
7. To be competent in the use of automated cleaning equipment and the use of benchtop sterilizers.
8. To be aware of the difference between detergents and disinfectants and the role of each in the decontamination processes and the consequences of using a disinfectant in the cleaning process.
9. To understand the rationale for keeping the lid closed when the ultrasonic cleaner is in use, and for changing the water daily or sooner if it appears to be heavily contaminated.
10. To be able to perform the foil ablation test to test the efficacy of the ultrasonic cleaning process and know how to interpret the results.
11. To understand the principles of the immersion method of manually cleaning instruments.
12. To know how to safely load instruments in the autoclave for proper sterilization.
13. To understand why sterile water for irrigation is recommended and why *freshly* distilled water is an acceptable alternative
14. To be aware of the importance of changing the water in the autoclave daily and the consequences of not doing so.
15. To be able to undertake daily and weekly user tests for benchtop sterilizers and know how and where to record the results



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16. To know whom to contact and what to do in the in the event of a cycle failure for bench top sterilizers.
17. To know how to record the information required for tracing instruments through the decontamination process.



Instrument Traceability Systems

Date	Time	Autoclave Number	Cycle number	Cycle Outcome	Tray Number	Patient Identification Number	Attach Print Out
			0001	Pass Fail	----- ----- ----- -----	----- ----- -----	
			0002	Pass Fail	----- ----- -----	----- ----- -----	
			0003	Pass Fail	----- ----- -----	----- ----- -----	
			0004	Pass Fail	----- ----- -----	----- ----- -----	
			0005	Pass Fail	----- ----- -----	----- ----- -----	