

Chief Medical Officer Group Castle Buildings Stormont Estates, Belfast, Northern Ireland BT4 3SQ

Our Ref: PEL (13) 13 Addendum 1

Date: 24 March 2015

For Action:

General Dental Practitioners

For Information:

Chief Executives HSC Trusts
Chief Executive HSC Board
Chief Executive HSC Public Health Agency
HSC Decontamination Leads
Chief Executive RQIA

Copy:

British Dental Association NI Chief Executive NIMDTA

Dear Colleagues

NORTHERN IRELAND GUIDANCE ON DECONTAMINATION IN PRIMARY CARE DENTAL PRACTICES: INTERIM GUIDANCE FOR THE CLEANING OF DENTAL HAND PIECES

Professional Estates Letter (PEL) (13) 13 issued on 1st October 2013 advised General Dental Practitioners on specific policy amendments to the guidance on decontamination in primary care dental practices that applies in Northern Ireland.

Following reported issues associated with handpiece/washer disinfector/detergent compatibility which are currently being investigated by the Northern Ireland Adverse Incident Centre (NIAIC), this Addendum to PEL (13) 13 provides guidance at Annex A on steps to take to check handpiece/washer disinfector/detergent compatibility; interim guidance for the cleaning of handpieces, should problems be identified; and the process for the reporting of potential compatibility issues to NIAIC. This interim guidance will be kept under review, pending the outcome of the NIAIC investigation and any other relevant information on this matter.

This addendum, together with PEL (13) 13 and the 2013 edition of HTM 01-05, can be found on the DHSSPS website at:

http://www.dhsspsni.gov.uk/index/hea/decontamination-general-dental-practices.htm

HSC Trusts are reminded that, in accordance with the Regional Decontamination Strategy, DHSSPS policy is that all HSC Community Dental Service decontamination requirements must be met from Sterile Service Departments (SSD) accredited to the essential requirements of the Medical Device Regulations.

Should you require any further information concerning the technical decontamination aspects of this letter please contact:

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Yours faithfully

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Chief Medical Officers Group

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Annex A: PEL (13) 13 Addendum 1

Interim Guidance for the cleaning of dental handpieces

Background

Following a report of reduced service intervals of handpieces being cleaned through a washer disinfector, the Northern Ireland Adverse Incident Centre (NIAIC) is currently conducting an investigation, together with the manufacturers of the handpieces and washer disinfectors, to determine potential compatibility issues and initiate corrective action as necessary. In accordance with NIAIC protocol, the UK regulator of Medical Devices, the Medicines and Healthcare products Regulatory Agency (MHRA), has been informed of the investigation.

This interim guidance has been produced to assist General Dental Practice teams in adopting an appropriate risk management approach should they experience compatibility issues associated with the cleaning of dental handpieces in a washer disinfector such as reduced servicing intervals of handpieces or increased frequency of repairs.

Step 1: Check the compatibility of handpieces with cleaning in a washer disinfector.

General Dental Practice teams cleaning handpieces in a washer disinfector are advised to check the handpiece and washer disinfector manufacturers' instructions to confirm that handpieces can be cleaned in your make and model of washer disinfector, and what is the correct procedure to be used.

Some handpieces are available on the market which are not compatible with cleaning in a washer disinfector and, if so, this will be outlined in the manufacturer's instructions for use. In such cases, and in accordance with the DHSSPS policy position, manual cleaning following a written protocol is acceptable.

Some handpiece manufacturers mark handpieces with an appropriate symbol to indicate that they can be cleaned in a washer disinfector however it is recommended that the manufacturers' written instructions should be checked to confirm compatibility with the washer disinfector process in operation. Some washer disinfector manufacturers provide type testing information related to the type of detergent validated for use in their machine, in addition to the compatibility of particular handpieces with the machine and detergent type. If this level of information is available, this should be noted and implemented as it provides a greater degree of assurance in terms of compatibility between handpiece/washer disinfector and detergent and the most effective cleaning of the handpiece.

Step 2: Check that you are using the type of detergent as recommended by the washer disinfector manufacturer.

It is important to note that changing the type of detergent from that recommended by the washer disinfector manufacturer may invalidate any warranty covering handpiece/washer disinfector compatibility.

Step 3: Check that you are lubricating your handpieces in accordance with the manufacturer's instructions.

Washer disinfectors might remove all lubricant during the cleaning cycle and so handpieces might require further lubrication after cleaning. The handpiece manufacturer's recommendations for lubrication should be followed. Handpiece maintenance equipment is available on the market and, although not validated for cleaning, their use may prolong handpiece life and can be particularly useful after handpieces are cleaned in a washer disinfector.

Step 4: Following completion of steps 1 to 3, if General Dental Practice teams continue to experience instances of reduced handpiece service intervals or increased frequency of repairs, please report this, together with associated evidence, to the NIAIC. Associated evidence to be retained for reporting to NIAIC includes the handpiece and washer disinfector manufacturers' instructions and associated records indicating increased instances of handpiece servicing or repair. Information on how to report to NIAIC is provided on the NIAIC website at:

http://www.dhsspsni.gov.uk/index/phealth/niaic.htm

In such cases, and <u>only following submission of an adverse incident report and</u> <u>associated evidence to NIAIC</u>, manual cleaning of affected handpieces following a written protocol can be undertaken as an interim measure. RQIA, as part of their regulatory inspections, will wish to see evidence that General Dental Practices have reported such cases to NIAIC prior to the adoption of an interim manual cleaning protocol. Practices should therefore retain a copy of reports to NIAIC together with records indicating when an interim manual cleaning protocol was adopted.

Please note that this interim guidance only applies to the cleaning of dental handpieces. Dental instruments, other than handpieces, designated as suitable for cleaning in a washer disinfector, should be cleaned using a washer disinfector in accordance with DHSSPS policy as outlined in PEL (13) 13.

This interim guidance will be kept under review, pending the outcome of the NIAIC investigation and any other relevant information on this matter.