THE SCOTTISH OFFICE

National Health Service in Scotland
Management Executive

NHS:
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1 May 1992

Dear Colleague

STERILE SUPPLIES INFORMATION LETTER NO 4
RE-STERILISATION OF ORTHOPAEDIC IMPLANTS

SUMMARY

1. Health Boards ask from time to time for advice about the re-sterilisation of orthopaedic implants when the original packing has been opened but the device, for various reasons, has not been used. General advice on the re-use and re-sterilisation of orthopaedic implants is given in British Standard 3531 part 17 1985 sections 2.6 and 7. The Management Executive's Sterile Supplies Policy Advisory Group (SSPAG) has provided further advice in the Annex to this letter.

ACTION

2. General Managers are requested to draw the Annex to the attention of orthopaedic surgeons, sterile supplies managers and Unit General Managers for information. Any decision as to whether to undertake re-sterilisation must be for the Health Board to make.

Yours sincerely

G W TUCKER
Directorate of Strategic Management

Addressees

For Action:

General Managers,
Health Boards.

For Information:

General Manager,
Common Services Agency.
General Manager, State Hospital.
General Manager,
Health Education Board for Scotland.
Chief Executives and
Chief Executive Designate,
NHS Trusts.

To be Circulated to:
Orthopaedic Surgeons and Sterile Services Managers for Information/Action.

To be Copied to: Unit General Managers for information

General Enquiries to:

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ANNEX

1. Obviously the best practice is to open items only when it is certain that they will be needed but it is accepted that this is not always possible and, in any event, the sterility of implant items is occasionally lost due to other mishaps. Any re-sterilisation presents 2 problems. The first concerns whether the item can be re-sterilised and, if so, what is the appropriate process. The second is that the product liability aspects concerning the sterility will be transferred from the original supplier to whoever undertakes the re-sterilisation process. The first problem is a technical matter and the second requires a value judgement to weigh up the costs saved by re-sterilisation against the risks the process attracts.

2. As an aid to addressing the first problem the information attached in the Appendix to this letter has been obtained from many of the manufacturers and suppliers who provide orthopaedic implants. Their co-operation is greatly appreciated. This information is reproduced in its entirety since editing may have lost nuances which were essential for comprehension. The information is provided strictly for those with the necessary skills and experience to interpret the information in a fashion guaranteed to achieve a sterile produce with a proper balance between thrift and risk.

3. Whilst the Sterile Supplies Policy Advisory Group are anxious that the advice from the suppliers of implants is given in its entirety there are inconsistencies in the information. The SSPAG had the following comments:

3.1 In the following pages some manufacturers state that items coated with hydroscapatite may be re-sterilised, others say not. The Group's advice is <u>not</u> to sterilise such items.

3.2 On page 10 the words "ethylene oxide autoclaving" are used. It is presumed that this should mean "ethylene oxide <u>or</u> autoclaving".

3.3 On page 16 (lines 1-3) the Group advise that if a dry heat sterilisation process is to be used the product should be brought to 160°C and held for 1 hour not ½ hour as stated.

3.4 On page 19 the Group is not satisfied that the reference at the foot of the page can be regarded as sound advice on which to base sterilisation practice.

The recommended times are:-

121°C (or 250°F) for 15 minutes

134°C (or 274°F) for 3.5 minutes

instead of the time/temperature combinations given in the chart on page 19.

APPENDIX

INDEX OF SUPPLIERS COMMENTS