

REVIEW OF THE DEEDS BULLETIN



Update of NIAIC Warning Notices Issued in 1996



*An Executive Agency of the Department of
Health, Social Services and Public Safety*

*Áisíneacht Feidhmeannach don Roinn Sláinte,
Serbhísí Sóisialta agus Sábháilteacht Phoiblí*

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1. EXECUTIVE SUMMARY

All the guidance in this device bulletin has been previously issued by the Northern Ireland Adverse Incident Centre (NIAIC) to health and social care organisations, and **no immediate action should be necessary**.

It provides a convenient source for **all the medical device warning notices issued during 1996, which are still in force**. It is intended as:

- a reference work;
- a resource for training;
- a checklist for risk managers.

Warning notices issued prior to 1996 that are still current are listed in our Device Bulletin DB(NI)2001/02. This is available on the NIAIC website: <http://www.dhsspsni.gov.uk/niaic>

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2. INTRODUCTION

In order to ensure that advice remains up to date, we have reviewed medical device warning notices warnings issued during 1996. This document contains reprints of those Safety Notices (SN) and Hazard Notices (HN) that are still relevant.

Organisation

The notices are grouped by Device Area, in order of date of issue. The appendix contains indexes by title and by reference number.

Editorial changes

The text of notices is reproduced in full but purely administrative headings and original contact details have been removed. To avoid confusions, paragraph numbers and some bullet points marking new paragraphs have been removed from the original text.

3. STERILE, SURGICAL AND IN VITRO DIAGNOSTIC DEVICES

3.1 Hazard Notice HN(NI)96/06 May 1996

Wooden tongue depressor

Manufacturer

Unknown

Problem

Use as limb splint for neonates leading to potentially fatal fungal infection.

Action

Immediately discontinue the use of wooden tongue depressors as limb splints.

Managers and staff are advised to:

- Cease the use of wooden tongue depressors as limb splints
- Use commercially available splinting materials
- Ensure that nursing procedures require that skin under splints is checked regularly

Background

- The Department has become aware of four confirmed cases of invasive mucormycosis due to *Rhizopus microsporus* at a neonatal unit in the West Midlands. Two infants died and a third underwent a partial limb amputation. A fourth infant recovered after aggressive anti fungal treatment.
- *Rhizopus microsporus* was isolated from wooden tongue depressors used as limb splints to immobilise limbs during venous access within the neonatal unit. Such fungi are common environmental organisms. Tongue depressors in another hospital have also been found to be contaminated with the same organism.

3.2 Hazard Notice HN(NI)96/12 July 1996

‘In-house’ manufactured spirit level used in central venous pressure (CVP) measurement

Problem

Spirit levels manufactured “in-house” and used in association with CVP measurement may be a potential reservoir for serious infection.

Action

Withdraw from use all such spirit levels

Managers and staff are advised to:

- Cease the use of spirit levels constructed ‘in-house’ under uncontrolled conditions
- Where spirit levels are required for use in CVP measurement, use commercially available items
- Ensure that suitable infection control procedures are followed at all times

Background

- The Department has become aware of an outbreak of multi-resistant *Pseudomonas aeruginosa* in a hospital ITU which infected a number of patients and led to the death of one patient.
- The same organism was isolated from an ‘in-house’ manufactured spirit level used in association with CVP measuring equipment. The spirit level consisted of a piece of bubble tubing filled with a mixture of tap water and chlorhexidine solution to provide colour, which was then formed into a loop and joined with tape.
- The organism was also isolated from the basin taps from where the water used to fill the spirit level originated. Such bacteria are common environmental organisms.

3.3 Safety Notice SAN(NI)96/23 May 1996

Need for decontamination of blood gas analysers used in near-patient testing

Summary

Those responsible for blood gas analysers used in near-patient testing are advised to ensure that they are regularly decontaminated because they may represent a potential source of cross-infection.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include infection control officers, Intensive Care Unit medical and nursing staff, Special Care Baby Unit medical and nursing staff, clinical chemistry consultants and laboratory managers, microbiology consultants and laboratory managers, and also consultants in Public Health Medicine who have responsibility for communicable disease control at area or district level.

Care should be taken to ensure that opportunities for cross-infection between blood gas analysers and patients are minimised. Measures to achieve this include rigorous adherence to equipment maintenance and decontamination procedures, and to hand-washing procedures after using the machine.

Boards/Trusts should ensure that if appropriate, this information is passed to all residential and nursing homes and private hospitals in their area.

Background

An association between infections in immunocompromised patients and the near-patient location of blood gas analysers has been reported^{1,2,3,4}. Strains of bacteria isolated from different components of blood gas analysers, including humidifier chambers, and accessories, have been shown to be indistinguishable from strains recovered from patients. It has not been established, however, how patients acquired these organisms.

Decontamination should be carried out in accordance with locally agreed procedures. Manufacturer's guidance may be found in the user manual.

The importance of good hygiene practices, including hand washing after each use of the equipment, should be drawn to the attention of all staff who use the instrument in the near-patient setting.

References

- ¹ Levy R, Hindley D T, Burman R, Haider S and Blease J. Unusual cause of pseudomonal infection. *BMJ* (1995) 310, 258
- ² Acolet D, Ahmet Z, Houang E, Hurley R and Kaufmann M E. *Enterbacter cloacae* in a neonatal intensive care unit: account of an outbreak and its relationship to the use of third generation cephalosporins. *J Hosp Inf* (1994) 28, 273-286
- ³ Henderson David K, Baptiste Ramona, Parillo Joseph and Gill Vee J. Indolent epidemic of *Pseudomonas cepacia* Bacteremia and Pseudobacteraemia in an Intensive Care Unit traced to a contaminated Blood Gas Analyzer. *Am J Med* (1988) 84, 75-80
- ⁴ Smith M J, Hart C A and Cooke K W I. Gentamicin-resistant *Klebsiella oxytoca* on a Special Care Baby Unit. *The Lancet* 1984; ii: p586-587

3.4 Safety Notice SAN(NI)96/29 June 1996

Extra-laboratory use of blood glucose meters and test strips: contra-indications, training and advice to the users

Summary

Staff who are responsible for extra-laboratory glucose testing, including near-patient testing, and for training self-monitoring diabetic patients, need to be aware that the clinical condition of the patient may be associated with the production of misleading results. Contra-indications and interpretation of results should be covered in staff training sessions.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include all medical, nursing, laboratory, pharmaceutical and other staff associated with areas where these devices are used, including outpatients clinics, accident and emergency departments, GP practices, community care units, supplies officers, customer care managers and liaison officers.

Managers who are responsible for extra-laboratory glucose testing, should ensure that users are aware of:

- the need to use testing devices in accordance with the manufacturers' instructions and to pay heed to any contra-indications stated in the instructions;
- all contra-indications known to be associated with the devices in use. Examples of contra-indications are listed in Table 1;
- the need to perform a laboratory measurement of glucose concentration using a venous blood sample, in cases where contra-indications are observed or suspected;
- the need for information regarding contra-indications to be incorporated into the training of all staff who are involved in extra-laboratory blood glucose measurement. Key action points on training are provided in Annex A.

Staff involved in training and advising self-monitoring diabetic patients should ensure that these patients are informed of potential sources of error when self-monitoring and should receive advice on how to interpret their results. Training should be periodically reassessed to correct errors and to reinforce good technique.

Table 1: Contra-indications associated with extra-laboratory blood glucose measurement

Contra-indications	Examples
Peripheral circulatory failure	severe dehydration, hyperglycaemic-hyperosmolar state with or without ketosis, hypotension, shock, peripheral vascular disease.
Severe dehydration	vomiting or diarrhoea, prescription drugs, eg diuretics, inability to recognise or respond to 'thirst' sensations, sustained uncontrolled diabetes.
Variations in blood oxygen tension	patients receiving intensive oxygen therapy.
High concentrations of non-glucose reducing substances in the blood	intravenous infusion of ascorbic acid.
High bilirubin values	jaundice.
Extremes of haematocrit	neonatal blood samples.
Dialysis treatment	
Hyperlipemia	

Background

- Recent incidents that have been investigated by MDA indicate that glucose meters and test strips can give clinically-misleading results when used on patients with hyperglycaemic hyperosmolar states with ketosis.
- A review of manufacturers' instructions and current literature reveals that there are a number of contra-indications, including hyperglycaemia, associated with the use of glucose meters and reagent strips. This highlights the need for clinicians to recognise that the potential for error exists when these tests are used as the sole basis for initial diagnosis and treatment of diabetes.
- These contra-indications are not confined to any particular blood glucose measuring device. Similar observations have been reported in the literature for most devices.
- The Department has received a number of reports concerning self-monitoring patients who have expressed concern at slight discrepancies in several blood glucose results. These reports emphasise the high degree of reliance that self-monitoring patients place on their glucose readings. This reliance should be taken into account when explaining the significance of glucose results to self-monitoring patients.
- This Notice draws attention to possible contra-indications and reiterates the need for appropriate training of staff and self-monitoring patients.

Annex A

Key points for the management of extra-laboratory equipment

1. General advice on the management of equipment was published in Health Equipment Information, Number 98, November 1990.
Managers are responsible for developing a policy for the use of extra-laboratory equipment and the training of the staff who use the equipment.
The advice given below, which covers important aspects of equipment selection, acceptance and training, should be followed in the management of extra-laboratory analytical equipment.
2. Careful and systematic selection of appropriate equipment is essential.
It is particularly important to ensure that the equipment has been designed for use by non-laboratory staff, and that it is suitable for its given clinical setting.
3. Care should be taken to ensure that consumables are compatible and give reliable results.
It is recommended that the pathology laboratory is involved in the purchase, and maintenance of all extra-laboratory equipment.
4. All staff who use extra-laboratory equipment must be adequately trained.
5. There should be written standard operating procedures for the equipment, which should be available to the user and preferably be attached to the equipment.
6. Training should include:
 - a. Basic principles of the measurement as well as the results to be obtained in normal and pathological states.
 - b. Demonstration of the proper use of the equipment in accordance with the manufacturer's specification.
 - c. Demonstration of the consequences of improper use.
 - d. Instruction in the collection of blood samples, including health and safety aspects.
 - e. Instruction in the importance of complete documentation of all data produced.
 - f. Appropriate calibration and quality control techniques.
 - g. Practical experience of the procedures, including a series of analyses that satisfy the instructor that the trainee is competent.
7. Independent quality control procedures on all extra-laboratory measurements should be carried out regularly, in collaboration with the pathology laboratory, to ensure that competence is maintained by all users and that the results are comparable with those produced by a quality controlled laboratory-based instrument.

3.5 Safety Notice SAN(NI)96/50 October 1996

Labotech automated microplate analyser: risk of sample contamination and carryover

Summary

False positive results have been observed with Labotech automated microplate analysers when sampling using the fixed metal probe option. These have resulted from sample carryover. The primary samples were also contaminated in some cases through using the fixed metal probe.

It is recommended that disposable tips are used for infectious disease assays. The fixed metal probe should only be used if it has been shown that carryover cannot affect the result of the assay.

This device is also supplied under the following names: Biokit Biomaster, Tek-Time and ETI-Lab.

Action

The following information should be brought to the attention of all those who need to know or be aware of it. This will include medical and technical laboratory personnel in virology, microbiology, immunology and haematology laboratories, nursing staff and blood banks.

Staff with management responsibility for laboratory testing should establish whether this device is being used with the fixed metal probe option. If it is, investigations should be carried out to assess the risk of carryover and the suitability of using the fixed metal probe.

It is recommended that disposable tips should be used for performing infectious disease assays where carryover is a potential problem. Other tests should be done with the fixed metal probe only if it has been shown that carryover cannot affect the result.

Users of other manufacturers' automated workstations should establish that carryover and, where applicable, primary specimen contamination does not occur.

Background

- The Department has received reports of false positive results with tests for hepatitis B. These resulted from sample carryover which also, in some cases, contaminated the primary specimens.
- Carryover has been demonstrated in three laboratories which used either the Biokit Biomaster (Labotech) automated workstations, supplied by Biokit Ltd, or the ETI-Lab supplied by Incstar Ltd. In each case, the metal probe sampling option was being used. The same instrument is also supplied as the Tek-Time by Organon-Technika.
- Investigations have indicated that contamination of the sample probe led to carryover.
- Investigations have also demonstrated contamination of stored primary patient samples from carryover.
- Additional information on this subject has been issued by the Public Health Laboratory Service (PHLS). Incstar is also providing supplementary instructions to users.

REHABILITATION AND TRANSFER EQUIPMENT

4.1 Safety Notice SAN(NI)96/05 January 1996

Walking aids – inspection and maintenance

Summary

Reports of incidents involving failure of walking aids, due to defective or worn products, are frequent. Managers and staff responsible for their issue are advised to ensure there is a formal inspection procedure for all walking aids.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include: supplies officers, works officers, nursing staff, physiotherapists, occupational therapists, community care and social services staff, hospices, ward sisters, safety officers, estate managers, appliance managers and works maintenance staff .

Staff responsible for the issue or loan of walking aids to patients should ensure that they are clean, safe and free from defect by implementing and maintaining a formal procedure for their inspection (further information is given in the Appendix to this notice, which is for guidance only). This procedure should address the need for inspection of the walking aid at various stages of supply. For example:

- following purchase or delivery to hospitals or stores;
- after storage;
- at point of issue to the patient;
- during long term issue in the community.

Boards/Trusts should ensure that if appropriate, this information is passed to all residential and nursing homes and private hospitals in their area.

Background

Incidents are regularly reported involving worn or defective walking aids.

Safety Information Bulletins SIB(86)75 issued November 1986, SIB(88)60 issued September 1988 and Safety Action Bulletin SAB(93)25 issued June 1993, all gave advice on inspection, maintenance, purchasing, storage and handling of walking aids.

Appendix to MDA SN 9604

Walking aids – guidance for inspection and maintenance

1. When taking delivery of walking aids an inspection should be made to identify any damage which may have occurred during transit. New items so damaged should be returned to the supplier for replacement. No attempt should be made to straighten bent or distorted legs.
2. When transporting walking aids, particularly walking frames, care should be taken to avoid rough handling and stocking which may apply excessive loads to the structure. Walking frames should be stored in an upright position and not on their sides. Lateral force should not be applied to frame legs during packing or storage. Frames should preferably be stored at ground level, rather than on high racks where damage could result from a fall.
3. Staff issuing walking aids should make users aware that care must be taken to avoid crush damage when transporting walking aids (particularly walking frames/rollators) in the boot of a motor car.

4. A routine maintenance procedure should be implemented to ensure that the frequency of inspections is adequate to maintain the walking aid in safe, serviceable condition and free from defect or damage, which should include the following:
 - i. Examination of the frame or structure for damage, in particular signs of deformation/bending and the condition of chrome plating (where applicable).
 - ii. Examination of any folding mechanism for security and correct operation (where applicable).
 - iii. All protective sleeves, caps and rubber tips must be fitted and be clean and serviceable.
 - iv. Examination of locking devices for security and correct operation e.g. height and adjustment catches.
 - v. Where applicable, wheel assemblies should be inspected for security of attachment and tyres inspected for damage or wear.
5. Where the status or condition of any walking aid is in doubt, the equipment should not be used.

4.2 Safety Notice SAN(NI)96/59 November 1996

Transfer and lifting equipment: problems associated with moving patients

Summary

A number of incidents have been reported where patients and staff have been injured when using equipment for moving, transferring and lifting patients. Investigation has revealed that often the equipment had not been used in accordance with the manufacturer's instructions.

Action

The following information should be brought to the attention of all who need to know or be made aware of it. This will include nursing staff, physiotherapists, occupational therapists, ambulance services, portering staff, carers, community care and social services staff who use transfer and lifting equipment. Copies of this notice should be forwarded to registered nursing homes, hospices and residential homes.

All staff who use equipment for moving, transferring and lifting of patients should be trained in its use; be familiar with the operating instructions; and be aware of safety precautions.

They should be able to select the appropriate equipment for the required transfer.

Care should be taken to ensure that the patient is correctly positioned.

Where fitted, safety belts, leg straps and leg supportors should be used, in accordance with the manufacturer's instructions, to secure the patient. Any locking device should be checked for secure engagement prior to the transfer.

Moving, transferring and lifting equipment should be manoeuvred using the handles provided or specified hand positions. The correct number of carers or operators should be in attendance at **all** times, and should perform their designated roles as recommended by the manufacturer or Health and Safety advisor.

Patients should not be left unsupervised on transfer and lifting equipment.

Particular attention should be paid to the training and familiarisation of new staff with equipment and accessories.

Boards/Trusts should ensure that if appropriate, this information is passed to all residential and nursing homes and private hospitals in their area.

Background

The Department has received reports of incidents involving patient moving, transferring and lifting equipment.

These indicate that the incorrect positioning of patients or the failure to use belts or straps correctly has resulted in:

- equipment becoming unstable and possibly toppling over
- patients falling from equipment
- patients moving or sliding on equipment while unsupervised.

5. DEVICES FOR DIAGNOSTIC IMAGING, THERAPY, MEASUREMENT, ELECTROSURGERY AND DISABILITY

5.1 Safety Notice SAN(NI)96/03 January 1996

Insufflators: risk of contamination

Summary

The Department has received reports that the internal gas circuits of laparoscopic insufflators became contaminated with patient fluids. Backflow of gas or patient fluids may occur under certain conditions during use. Such contamination may not be obvious to the user and creates a cross infection risk.

Users are advised to take precautions to prevent contamination occurring.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include medical and nursing staff, infection control officers, medical engineering departments, safety officers, nursing staff, endoscopy units and day procedure units.

The following precautions should be taken during the use of insufflators to minimise the risk of interior contamination:

- a) Always follow the manufacturer's instructions for use and ensure that any bacterial filter/liquid trap assembly which is provided or recommended it is fitted, used and disposed of appropriately.
Users should take advice from manufacturers as to the effectiveness of filters.
- b) Switch on the insufflator and allow gas to flow to atmosphere for 3-4 seconds before connecting the patient.
- c) While the insufflator is connected to a patient the pressure indicator should be monitored. Any sudden drop or rise in pressure should be investigated.
- d) At the end of a procedure disconnect the patient before the insufflator is switched off.
- e) When the insufflator is being used with a gas recirculation system then:
 - Ensure that all tubing and connectors are set according to the manufacturer's instructions;
 - the insufflator should then be started
 - the patient connected; and
 - the recirculation system started when required.
 - When the procedure has been completed, the recirculation system should be stopped and disconnected from the patient by reversing the above sequence.

Boards/Trusts should ensure that if appropriate, this information is passed to all residential and nursing homes and private hospitals in their area.

Background

- 3.1 The Department has received reports from manufacturers that contaminated components were found in insufflators undergoing routine maintenance. An official report from Canada supports this ¹.
- 3.2 Contamination can arise when the pressure in an insufflator becomes less than that of a patient. Under these circumstances a reverse flow of gasses or fluids can take place, from the patient into the insufflator. The circumstances that this can occur are outlined below. Either one or more of these factors could be present at the same time.

- 3.2.1 A vacuum can be produced in insufflators where the design allows CO₂ gas to become trapped in the internal components, after switching of the insufflator. The trapped CO₂ very rapidly permeates through the silicon materials to the surroundings causing a pressure lower than atmospheric to be created in the insufflator. Thus insufflators that have not been in use for some time could have a pressure less than atmospheric in their internal components. This may not be easily noticed prior to use.
Most makes of insufflators use silicon rubber materials in the construction of various components, eg tubing.
- 3.2.2 Experiments carried out on insufflators to measure the insufflator pressure have given results, for example, of 13 Kpa and 40 Kpa (100 and 300 mm of Hg) below atmospheric pressure, after the insufflator was 'at rest' for 25 and 120 minutes respectively. These were static pressures recorded at the patient connection port of the insufflator.
- 3.2.3 The insufflator may be at a lower height than the patient with respect to the ground. Under these circumstances if the insufflator is switched off before the patient is disconnected, then it is possible for fluids to flow back into the insufflator and cause contamination. Similar problems can exist whilst the CO₂ cylinder is being changed.
- 3.2.4 Application of mechanical pressure on the abdomen of a patient can force contaminants into the insufflator.
- 3.2.5 Reservoirs used with recirculation systems can become overfull and then it is possible for contaminated fluids to be forced into the insufflator.

References

- ¹ Alert No. 106 February 1995, 'Contamination of Laparoscopic Insufflators with Patient Fluids'.
Publishers: Medical Devices Bureau, Environmental Health Directorate, Health Protection Branch,
Tunney's Pasture, Ottawa, Ontario, Canada K1A 0L2 (Tel: 001 613 952 7125), (Fax: 001 613 957 7318).

5.2 Safety Notice SAN(ND)96/17 March 1996

Risk of skin burns from lead adaptors used with electrosurgical equipment

Summary

The Department has received reports that most adaptors used with electrosurgical equipment have accessible bare metal parts thus posing a risk of electrosurgical burns. The risk is increased when using spade or hook connectors.

The adaptors referred to in the reports did not conform with the basic safety standards for medical devices.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include all medical and nursing staff, medical engineering departments, safety officers and GPs.

Users are advised to avoid using adaptors. It is recommended that only leads and connectors designed for direct connection to the electrosurgical equipment should be used.

Users are advised to follow the manufacturer's recommendations about using, storing, cleaning, checking and re-using electrosurgical leads and connectors.

Boards/Trusts should ensure that if appropriate, this information is passed to all residential and nursing homes and private hospitals in their area.

Background

- The type of adaptors investigated permit the connection of smaller size lead connectors to larger size socket inlets on electrosurgical equipment. Such adaptors also permit the connection of leads with spade or hook connectors.
- The Department has received reports from hospitals of burns to users when adaptors were touched accidentally during a procedure. If such connectors were a part of the electrosurgical generator these would fail to meet IEC 601-1¹ safety requirements.
- Other adaptors which can be connected to multi-pole sockets on the equipment are also available. When using adaptors it is possible to make some of the safety features of the equipment inoperative, for example the feature that monitors whether the return electrode is currently attached onto a patient.
- It is probable that a large number of these adaptors are in use because they are seen as a convenient method of connecting different makes of leads to electrosurgical equipment. This practice may appear at first to be an attractive economy measure, but it can jeopardise the safety of patients and users.

Reference

¹ IEC 601-1: 1988 Medical Electrical Equipment requirements for safety: for example clauses 16 and 56.3

5.3 Safety Notice SAN(NI)96/26 May 1996

X-ray equipment: safety of footswitches used under adverse conditions

Summary

A number of incidents have come to light where footswitches used under adverse conditions have malfunctioned. This could cause injury to the patient/user and damage to the surroundings. Certain precautions are recommended to avoid this situation.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include radiologists, radiographers, radiation protection advisers, radiation protection supervisors, medical physics and works staff concerned with maintenance of equipment, fire officers, safety representatives and supplies officers.

Equipment meeting BS 5724:Part 2.7, is designed to withstand certain conditions including fluid penetration but the following additional precautions are recommended:

- ensure that the condition of the footswitch is assessed during regular maintenance of the equipment,
- ensure that any sign of malfunction is immediately reported and corrective measures taken, and
- if exposure to corrosive fluid cannot be avoided, the footswitch should be enclosed in a plastic bag, provided that this in no way inhibits normal operation and is approved by the manufacturer.

Boards/Trusts should ensure that if appropriate, this information is passed to all residential and nursing homes and private hospitals in their area.

Background

- The constructional requirements for cord connected footswitches are laid down in BS 5724:Part 2.7. This requires not only that footswitches be drip-proof and sealed against floor washing but also that they shall be water-tight (this includes the cable entry into the switch). In addition, the footswitches connected to equipment by flexible cord shall not contain conductors or components operating at voltages greater than 24V ac or 50V dc.
- However, incidents concerning footswitches used with fluoroscopic X-ray equipment from a variety of manufacturers have shown the need for supplementary precautions. For example, in an environment where they are exposed to spillage of saline solutions, as in urological examinations.
- Under the influence of corrosive liquids, switches can become mechanically ineffective and this can lead to unintentionally prolonged exposures. Even when the equipment, including the footswitch, complies with BS 5724:Part 2.7, it is still desirable to take additional precautions against damage from corrosive fluids.

5.4 Safety Notice SAN(NI)96/42 September 1996

X-ray contrast media injectors: risk of air embolism

Summary

An incident has been reported to the Department in which the injection of air instead of contrast medium led to a fatal air embolism. Local procedures for contrast injector operation should include checks to ensure syringes are correctly loaded and filled. Users should ensure that the procedures are available locally and are followed when contrast injectors are used.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include directors of radiology, radiologists, radiographers, radiation protection supervisors, radiation protection advisers, and safety representatives.

Staff using contrast media injectors should be trained in their use and be familiar with current operating procedures.

The procedures for using contrast injectors should be available locally and should include checks to ensure that syringes are correctly loaded and filled with contrast media in accordance with the manufacturers instructions.

Users should ensure that, if the injector design requires syringes to be loaded in such a way that they are initially fully of air, the operator first moves the plunger forward to empty the syringe. This is to reduce the risk of an air filled syringe being mistaken for one full of contrast medium.

Empty syringes should not be left in injectors at the end of a procedure.

When connecting catheters and syringes, steps should be taken to ensure that no air is introduced into the system.

Staff should be aware of the risks associated with the injection of air.

Boards/Trusts should ensure that if appropriate, this information is passed to all residential and nursing homes and private hospitals in their area.

Background

- In a recent incident an air filled syringe was thought to be full of contrast medium and was injected into a patient, who died from an air embolism.
- An empty, unused syringe had been left in the injector at the end of a session. Staff using the equipment in a following session mistakenly assumed the syringe had been filled.
- The injector involved in the incident was a Medrad Mk V, but no fault was found with the device when it was examined after the incident.
- In this and other types of injector, new syringes are loaded with the plunger fully retracted to keep the barrel of the syringe free from contamination and to aid plunger connection.

5.5 Safety Notice SAN(NI)96/47 October 1996

Detachable mains supply leads for use with medical devices. Reported problems

Summary

A number of problems have been reported with detachable mains supply leads. Some of these leads posed electric shock risks to patients and users; in others there was an overheating risk with the potential for fire.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include medical and nursing staff, medical physics, EBME departments, maintenance and engineering staff, safety officers, Estates Officers, Facilities Managers, Risk Managers, Fire Officers, Supplies Managers and users of electrically powered medical equipment in the community.

Detachable mains supply leads used with medical devices should be regarded as part of the device and therefore users should ensure that:

- maintenance procedures should include periodic inspection of such leads;
- faulty leads should be removed from use. If the fault is considered serious and likely to occur with other users, then the Department and the suppliers should be informed;
- leads are used and stored with care so that the whole cable assembly is not under mechanical strain;
- newly supplied leads are inspected before putting into service;
- cleaning should be performed according to the manufacturers' recommendations and without jeopardising the electrical integrity of the cables and insulation.

Inspection methods vary from visual checks to measurements of cable characteristics, suggested methods are outlined in the Appendix to this notice.

Boards/Trusts should ensure that if appropriate, this information is passed to all residential and nursing homes and private hospitals in their area.

Background

The purpose of this bulletin is:

- to remind users of the checks that should be carried out on detachable mains supply leads as recommended in previous publications²;
- to inform users of the various problems that have been reported to the Department; and
- to summarise some acceptance checks.

A number of reports received by the Department related to both newly purchased cables and those in use. The problems included:

- The outer insulation sheath of the cable had become detached from the anchorage point at the end connectors. As a result the inner (insulated) conductors were exposed. Most reports referred to this occurring at the mains connector end, the end that connects to the equipment, as opposed to the mains plug end.
- A considerable number of moulded mains plugs are manufactured by welding two or three plastic parts together. A number of reports referred to the failure of the weld that was bonding the plastic cover onto the plug. The plastic covers became detached and consequently exposed live terminals.
- Reversal of Neutral and Earth wires between the plug and the mains connector.
- Cables being supplied with European or other types of moulded plugs which are not suitable for use in the UK. This may encourage users to use mains adaptors which often lack protection to earth connection. **This practice is not recommended.**

- Unclear information as to whether the current rating of the cable connecting the two end connectors is compatible with the current rating of the end connectors. For example, a 13A plug could be marked to carry a 5A fuse because the cord has been constructed to carry a maximum of 5A current. If the marking is not clearly visible a 13A fuse could be inserted in this plug and would not therefore be protecting the cable.
- The fuse was inserted in a plug without the fuse carrier. When the plug was inserted in the wall socket there was a short to earth. This occurred because the live terminal of the fuse was not inserted fully in its housing and it was protruding. The 'live' end of the fuse touched the metal case of the wall socket, thus fusing the mains supply at the distribution board. **Fuses should be inserted correctly using the fuse carrier provided.**
- Inadequate connections between the wires and their terminals. These connections are normally embedded in the moulded connectors and are not accessible. If there is a poor connection at these points the resistance is increased, it is likely to overheat and could become a fire hazard^{1,2}.

Because of a number of problems reported, two of the manufacturers of mains leads have recently recalled all leads from the affected batches^{3,4}.

References

1. HEI 95 'Code of Practice for Acceptance Testing of Medical Electrical Equipment', section 2.2.4.1.
2. Safety Action Bulletin SAB (92)14 Electrical leads and power supply cords: 'Incidents of overheating and incorrectly colour coded conductors'.
3. Safety Action Notice SAN(NI)95/37 Medix Two-pin Universal Mains Leads: Risk of Electric Shock.
4. Publication of recall of mains leads in the national press 4 of March 1996.

Standards and regulations

EN 60 320: Part 1. Appliance connectors.

Plugs and Sockets Etc (Safety) Regulations 1994. Statutory SI 1994/1768.

Appendix to SAN(NI)96/47

Suggested inspection tests for mains leads used with medical devices.

Checks should include:

- To check that the outer insulation sheath is adequately anchored at both ends of the cable.
- That the plug and mains connector do not show signs of damage that could result in these connectors fracturing.
- That the correct rating fuse is held in place with the appropriate fuse holder. Correct rating fuse means that it is correct for the current rating of the whole cable assembly.
- That the earth line is not transposed with other lines.
- That each cable makes a good electrical contact with its end terminals at both ends. Measure the resistance between the end terminals for each wire. Suggested acceptable value not greater than 0.1 ohms.

CRITICAL CARE DEVICES

6.1 Hazard Notice HN(NI)96/09 June 1996

Phototherapy devices for the treatment of neonates and infants

Manufacturer

All manufacturers of phototherapy devices

Problem

Potential burns to patients

Action

Ensure that phototherapy devices are used in accordance with manufacturers' instructions

Managers and staff are advised that to ensure that the manufacturers' instructions for the use of phototherapy devices are available and followed. In particular ensure that:

- The lamp is at the correct height above the patient
- Any filters required for safe operation are in place
- The correct type of replacement lamps are used, as recommended by the manufacturer
- The device is regularly inspected/maintained
- Users are fully trained in the safe use of the device

Background

- The Department has received reports of phototherapy devices not being used according to the manufacturers' instructions, resulting in burns to patients.
- In a recent case a phototherapy lamp was used without the required filter in place and was positioned too close to the patient.
- Staff may not be aware of the operating instructions for these devices, in particular, how to determine the correct distance between the patient and the lamp.

6.2 Hazard Notice HN(NI)96/13 July 1996

Ohmeda Tec 6 Desflurane anaesthetic vaporizer; mains lead

Manufacturer/supplier

Ohmeda/Pharmacia & Upjohn

Problem

Use of mains leads other than those supplied by Ohmeda for the Tec 6 Desflurane vaporizer can interfere with the correct functioning of adjacent vaporizers. This may result in reduction or absence of anaesthetic agent being delivered to the patient from the adjacent vaporizer.

Action

Ensure that only Ohmeda mains leads are used with the Tec 6 Desflurane vaporizer and that when routing the mains lead from the Tec 6 to the electrical supply it does not interfere with the operation of adjacent vaporizers or the 'Selectatec' locking mechanism.

Users should check that the correct mains leads are available and are used with the Ohmeda Tec 6 Desflurane vaporizer (Ohmeda part No. 1107-3187-000 long mains lead, 1107-3191-000 IEC mains lead). Both leads have a 90° angled plug for connection to the vaporizer.

Users should also ensure when routing the mains lead from the Tec 6 vaporizer to the electrical supply that it does not interfere with the operation of adjacent vaporizer or the 'Selectatec' locking mechanism.

Refer to the manufacturer's instructions and warnings covering the vaporizer mounting procedure and the need to ensure that the backbar area is clear of physical obstructions.

Background

The Department have been informed of a case of a patient suffering from an inadequate depth of anaesthesia (awareness) resulting from a reduction in or absence of anaesthetic agent being delivered from a vaporizer adjacent to an Ohmeda Tec 6 vaporizer. Investigation has indicated that a standard mains lead with a straight plug at the vaporizer connection had been used with the Tec 6. This had interfered with seating of the adjacent vaporizer onto the 'Selectatec' backbar allowing the anaesthetic agent to leak from the system and not reach the patient.

A similar case to this was recently reported in Anaesthesia where the mains cable from a Tec 6 vaporizer was passed over the 'Selectatec' backbar and interfered with the 'Selectatec' locking system. No volatile agent could then be delivered.

There is the potential for the operation of vaporizers to be affected by any form of physical obstruction within the area of the backbar, users should refer to existing instructions which describe retainment of the mains lead and correct routing of the cable.

6.3 Hazard Notice HN(NI)96/15 August 1996

Nursing and transport incubators

Manufacturer/supplier

Various

Problem

Electrical devices not designed for use in oxygen enriched atmospheres have been reported as being used inside nursing incubators. This practice increases the risk of fire.

Action

Only electrical equipment, (mains or battery powered) that has been designed specifically for use in oxygen enriched atmospheres should be used inside incubators.

Users of nursing and transport incubators should be made aware of the fire hazards, resulting from using electrical equipment, including battery operated devices that have not been designed for use in oxygen enriched atmospheres in incubators.

Users should confirm that if placing electrical devices such as syringe/infusion pumps and apnoea monitors outside the incubator requires the use of extension sets or cables that the performance of the device is not impaired. In the case of equipment which has electrical connections to patients, e.g. monitoring equipment with patient connected probes, advice should be obtained from the manufacturer as to the device's suitability for use in this environment.

Background

The majority of incubator manufacturers state in their instructions for use that electrical equipment should not be used inside incubators.

Reports have been received of syringe pumps and apnoea monitors being used inside incubators. Neither the syringe pumps nor the apnoea monitor were designed for use in oxygen enriched atmospheres.

6.4 Safety Notice SAN(NI)96/13 February 1996

Drager Oxylog ventilator pressure relief valve risk of failure when autoclaved using the 134°C cycle

Summary

The Department has received a report of the pressure relief valve on a Drager Oxylog ventilator becoming disconnected from its patient connection block after autoclaving using the 134°C cycle. Drager have confirmed that these valves should not be autoclaved using the 134°C cycle, and recommend that disinfection is used. Users who prefer to autoclave these valves should use a 121°C cycle in a porous load sterilizer.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include medical, nursing and technical staff associated with the following departments and units: anaesthetic, medical and surgical, obstetrics and gynaecology, operating, ITU, CCU, neonatal units, paediatric intensive care, accident and emergency, together with: EME or EBME, Hospital Sterile Supplies, CSSD, TSSU, HSDU, equipment maintenance engineers and safety liaison officers.

Staff should ensure that Drager Oxylog Pressure Relief Valves (part number 8405390) are not autoclaved using the 134°C cycle.

Background

- The Department has received a report of the valve becoming detached from the body of an Oxylog pressure limiting valve assembly during use.
- The detachment was the result of the bonding between the valve body and the patient connector assembly failing.
- The failure of the bonding was caused by the valve assembly being autoclaved at 134°C.
- Drager recommends disinfection as a general procedure for this valve as described in the short instructions for use for the pressure limiting valve, part 8405390, 2nd edition, September 1995. If autoclaving, only a 121°C porous load cycle should be used.

6.5 Safety Notice SAN(ND)96/15 March 1996

Modification of Baxter Flo-Gard infusion pumps

Summary

Baxter Healthcare Ltd are conducting an upgrade programme on the installed base of Flo-Gard 6100 and 6200 infusion pumps. 80% of all Flo-Gard pumps have been modified to date.

Users should always use the administration set recommended by the manufacturer, which will depend on the type of pump and its modification status.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include all medical, nursing and technical staff in all departments and community units where these pumps are used and supplies departments that stock the IV administration sets.

The Stores/Buying departments and all staff responsible for ordering infusion sets should be made aware of the modification and which infusion sets are required following modification.

The sets that should only be used with unmodified pumps or those that should only be used with 6201 or modified pumps are shown in the following table.

Unmodified pumps should only be used with the sets listed below	6201 or modified pumps should only be used with the sets listed below
C0117 C0164	C9601 C9602
C0124 C0180	C9603 C9604
C0142 C0360	C9605 C9606
C0163 C0361	C9607 C9608
C2579	C9609

Users can identify a modified pump by the presence of a white label fixed to the device indicating the correct infusion sets to be used. A sample of the label is shown in the appendix.

The issues addressed by this notice refer only to sites where Baxter Flo-Gard infusion pumps are used. For sites which use Baxter sets for gravity infusion only, no action is required.

Background

Baxter Healthcare Ltd are standardising on a single size pump compatible administration set. The lumen size is changing from 2.8 mm and 2.6 mm nominal diameter. Existing pumps are being modified.

The modification is carried out by Baxter Healthcare Ltd free of charge on users' sites and at this time all "old" sets are replaced by "new" sets on a one for one basis.

The Department has recently received two reports from one hospital where confusion about the modification existed, particularly regarding which sets were compatible with modified pumps.

Administration sets for use on the 6201 pump and the modified 6100/6200 pumps can further be identified by the location of a dark blue anti-free flow slide clamp fitted between the roller clamp and the chamber. Furthermore, the printing on the pouch packaging is in green ink.

The time table to complete the upgrade has been agreed with the Department and is expected to be completed by October 1996.

Advice on infusion systems is given in the Device Bulletin DB 9503.

APPENDIX

Sample of the label attached to modified pumps

IMPORTANT

Use only Baxter
Flo-Gard compatible
administration sets
with one of the
following codes:

C9601	C9602
C9603	C9604
C9605	C9606
C9607	C9608
C9609	

PLEASE NOTE

When removing set
from pump, ensure
roller clamp is fully
closed.

6.6 Safety Notice SAN(NI)96/35 August 1996

Spacelabs ECG monitors software fault recall

Summary

Spacelabs Medical have initiated a recall of a number of ECG monitors and modules due to a software fault that can result in an incorrect waveform display.

Users of the equipment listed in the appendix who have not been directly approached should contact Spacelabs at the address below for a free upgrade.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include anaesthetists, medical, nursing and technical staff in coronary and intensive care, operating theatres, recovery rooms and cardiology departments, electronics and medical physics staff and safety liaison officers.

Users should identify the devices listed in the appendix and ensure it is upgraded by Spacelabs Medical. Users who have equipment that has not been upgraded should contact Spacelabs Medical at the address below for a free upgrade.

In the meantime Spacelabs recommend that the equipment can be used with vigilance. If sudden changes in the patient's rhythm are observed and the heart rate indicator is not flashing, the occurrence of the fault can be found by disconnecting the patient cable. If the ECG display clears there is no software fault. If the waveform remains, pull the module from the housing and re-insert it and reconnect the patient cable.

Background

Spacelabs Medical have identified that some earlier manufactured ECG products may have a software fault that results in an incorrect waveform display. The incorrect wave form is displayed as a repetitive morphology at about 210 bpm or a rhythm that resembles asystole. In either case the heart rate indicator does not flash.

Spacelabs have initiated a software upgrade. However due to the age of some of the products not all users have been contacted.

Appendix

Biotel 300 Telemetry receivers
Model numbers 90332, 90334, 90336 and 90338 with software version 5.42.07

Alpha PC dual ECG module
Model numbers 90407 and 90408 with software version 5.42.07 or earlier

PC dual adult/neonatal ECG module
Model number 90418 with software version 5.42.07 or earlier

Integrated multiparameter PCMS module (basic)

Model number 90425 with software version 1.42.07 or earlier

PC multilead ECG/ESIS module and ST Seg. Anal.

Model number 90427 with software version 1.42.07 or earlier

Integrated multiparameter PCMS module basic + CO, HC dual lead

Model number 90432 with software version 1.42.07 or earlier

6.7 Safety Notice SAN(NI)96/34 August 1996

Lung ventilator: Ohmeda OAV 7750: potential failure of power supply

Summary

Ohmeda has issued a Service Bulletin (SB00314) advising users of OAV7750 ventilators of a potential failure of the DC to DC converter, part number 15017723, in the ventilator's power supply. The failure of either of two resistors due to overheating will result in the ventilator's power supply failing. Users are advised to check these components and replace the converter board if they show signs of overheating.

Action

The following information should be brought to the attention of all those who need to know or be aware of it. This will include medical, nursing and technical staff, where appropriate, associated with the following departments and units: surgery, anaesthesia, operating theatres, EME or EBME and equipment maintenance engineers, Intensive Care Units and Safety liaison officers.

Staff responsible for the use or maintenance of Ohmeda OAV 7750 ventilators should ensure that the resistors R1 and R2 on the DC to DC converter board in the ventilator's power supply are examined for signs of overheating. If overheating is evident, i.e. the resistor colour bands (brown, grey, red and gold) cannot clearly be distinguished, Ohmeda should be contacted at the address below for a replacement board, free of charge.

Users who require more details in identifying the resistors or who wish Ohmeda to inspect their ventilators should contact Ohmeda at the address below:

Background

- Ohmeda has become aware of a potential failure of the DC to DC converter board, part number 15017723, in the OAV 7750 ventilator's power supply resulting in the ventilator failing and activation of its power fail alarm.
- The potential failure is the result of either two resistors, R1 and R2 failing because of overheating.
- The probability of overheating is increased if the ventilator is left powered on when not in use or left switched on when fitted to an Excel anaesthetic machine which is switched off but still connected to a mains supply.
- Ohmeda has issued a Service Bulletin number SB 00314 to advise users of the problem and the corrective action.

6.8 Safety Notice SAN(NI)96/57 November 1996

Demountable anaesthetic agent vaporizers

Summary

The inadvertent mal-positioning of anaesthetic agent vaporizers has led to leakage from the anaesthetic gas delivery system, which may adversely affect the administration of an anaesthetic. It is essential that manufacturer's instructions and/or recommendations for mounting vaporizers are followed.

Action

The following information should be brought to the attention of all who need to know or be made aware of it. This will include medical nursing and technical staff in all units and departments where these devices are in use including all operating departments, dental, and intensive care units, High Dependency Units together with medical physics, EBME, supplies, customer care, risk managers and safety liaison officers.

Those responsible for the use and management of anaesthetic agent vaporizers should ensure that all staff:

are made aware of the contents of the manufacturer's instructions and are trained to ensure that the instructions are carefully completed at all times. Particular attention should be paid to instructions on mounting.

need to be aware that the function of the anaesthetic machine must be checked prior to use on a patient and following any changes of vaporizer.

Background

- The Department has investigated several incidents in which the output of the anaesthetic machine was significantly reduced due to the inadvertent mal-positioning of anaesthetic vaporizers during mounting. Subsequent use of the equipment has led to awareness during surgery potentially causing considerable distress to the patients.
- Incidents have been reported of vaporizer securing connection systems that can be rendered ineffective if manufacturer's instructions are not followed exactly. Appropriate checks should be performed to confirm the correct function of the anaesthetic machine and the vaporizer to be used before administering anaesthesia and after any change of the vaporizer during use.
- Incidents are reported of vaporizer locking levers being rotated before the vaporizer is located on the ports. The vaporizer can then appear to be located correctly, whilst the locking mechanism is in the locked position but is not engaged. The failure of correct fixation of the location screw may on its own or when combined with a slight tilting of the vaporizer cause a substantial leak of fresh gas.
- The Department wish to emphasise the importance of checking anaesthetic machines and breathing devices in the prevention of injury to patients. The Association of Anaesthetists of Great Britain and Ireland has published the checklist for anaesthetic machines (1990) for checking devices **pre use and following any changes during use**, such as the changing of a vaporizer. This document should be available for use by all working with anaesthetic devices.

7. IMPLANTS AND MATERIALS

7.1 Hazard Notice HN(NI)96/10 June 1996

Silicone fluid used for body contouring

Manufacturer

No manufacturers are currently known to supply silicone fluid for this purpose

Problem

Use of silicone fluid for the augmentation of body tissues

Action

Silicone fluid is not considered suitable for the augmentation of body tissues and is not sold for this purpose.

Managers and staff are advised that:

Silicon fluid should **NOT** be used as a body contouring material for the augmentation of body tissues

Background

- Silicon fluid has been used in the past for body contouring purposes. A number of local reactions to silicone fluid in these procedures were recognised in the 1970s and silicone fluid was no longer considered suitable for this purpose. Neither manufacturers nor professional bodies have recommended silicone fluid for this purpose since that time.
- Injectable materials intended for body contouring can currently be marketed either under the Medicines Acts or under the Medical Devices Directive. According to the Medicines Control Agency's records, no silicone fluid **Products** are currently licensed for the augmentation of body tissues. The Department is not aware of any **Products** of this nature having a CE Marking, nor of any manufacturer seeking CE Marking.
- The Department has recently been informed that silicone fluid is being used in the independent UK health sector for cosmetic augmentation by injection. In light of the reactions identified in the 1970s, silicone fluid is not considered suitable for this purpose. The Department has not as yet identified any manufacturer who supplies silicone fluid for this purpose but will be pursuing this investigation.
- A number of alternative injectable materials for body contouring are available with either CE Marking or product licences.
- This advice does not apply to other uses of silicone such as silicone gel breast implants.

7.2 Safety Notice SAN(NI)96/04 January 1996

Risk of ignition of sealed polyester vascular grafts/patches

Summary

The Department has been informed of incidents of ignition of polyester fabric by electrocautery while cutting dry sealed vascular grafts, cardiovascular patches or valved grafts/conduits during implantation.

Action

The following should be brought to the attention of all those who need to know or be aware of it. This will include all cardiothoracic surgeons, vascular surgeons, general surgeons, theatre nursing staff, operating department assistants and safety liaison officers.

Managers and staff are advised to:

- ensure that steps are taken to prevent the ignition of dry sealed polyester fabric by the cautery cutting tool. This may include:
 - ensuring the polyester remains damp during cauterisation by thorough soaking of the fabric in saline; or
- using low temperature cautery at approximately 500°C/900°F.
 - follow any current precautions or warning in the manufacturers' instructions to avoid burning of the polyester and be aware of any changes in the instructions.

Background

- The Department has been informed of two UK incidents in which the vascular graft forming part of a valved conduit caught fire during electrocautery at implantation. Neither incident resulted in injury. Five similar incidents outside the UK have been reported involving valved conduits or tubular grafts. All incidents involved products made from sealed woven polyester fabric.
- Electrocautery is recommended for cutting most **woven** (as opposed to knitted) polyester fabrics to prevent fraying, and a cautery cutting tool is sometimes provided for use with these products. However, it is important to be aware of the potential for ignition of the polyester if it is coated in a protein sealant. Some manufacturers' instructions recommend soaking the fabric in saline prior to cutting or the use of a low temperature (approximately 500°C/900°F) cautery tool.
- The risk of ignition is significantly lower for unsealed grafts. This is because polyester will not usually support burning in the absence of a coating. In addition, these grafts will typically be moist with blood at implantation as they require pre-clotting.
- Carbomedics and Vascutek amended their instruction for use in April 1994 to address this hazard, Meadox Medicals Inc, Medtronic, and St Jude Medical intend to include this new precaution in their instructions in the near future.
- The following are examples of products affected by this Notice:

CarboMedics Carbo-Seal® aortic valve conduit

Meadox® Hemashield® Woven Double Velour: Vascular Graft and Fabric (patch)

Medtronic Aortic Valve Collagen Impregnated Conduit Z7700xx

St Jude Medical® aortic valved graft: CAVG-304 & CAVG-404

Vascutek Gelweave® woven vascular graft

However, all dry sealed woven polyester grafts, patches or valved conduits, may have the potential for ignition by electrocautery, and the above list should not be considered exhaustive.

7.3 Safety Notice SAN(NI)96/30 June 1996

Zirconia ceramic heads for modular total hip femoral components: advice to users on resterilization

Summary

The Department is aware that steam sterilization may lead to surface roughening of zirconia ceramic heads. As a consequence of the roughening, increased wear of the ultra high molecular weight polyethylene (UHMWPE) acetabular component has occurred necessitating early revision. In the interests of improved safety, the zirconia ceramic component suppliers have advised that if resterilization is considered necessary then steam sterilization must not be used.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include directors of orthopaedic and surgical units, orthopaedic surgeons, safety liaison officers, Accident and Emergency Departments and Sterile Service Departments (CSSDs, HSDUs, TSSUs and HSSDs).

Managers and staff are advised not to use steam sterilization for the resterilization of zirconia ceramic heads.

Orthopaedic surgeons may wish to consider regular radiological examination of patients who have been implanted with zirconia ceramic heads known to have been resterilized using steam, in order to monitor for radiographic evidence of osteolysis.

Background

In recent months a limited number of zirconia ceramic heads were retrieved from patients during revision surgery, due to osteolysis. Retrieval analysis showed surface degradation of the zirconia ceramic heads and an unexpectedly high amount of wear on the UHMWPE acetabular component, when compared to levels typically seen with zirconia ceramic heads.

The surface degradation of the zirconia ceramic heads has been attributed to the use of steam during re-sterilization of the component. The combination of steam and elevated temperature can lead to a change in crystal structure of the zirconia. It is believed that this results in a slight roughening of the ceramic surface, which can lead to increased wear of the UHMWPE acetabular component during articulation. UHMWPE wear debris has been implicated in osteolysis. The casual relationship between the material degradation and osteolysis has not been conclusively established.

Zirconia ceramic heads are supplied sterile to hospital customers. It is known that one of the retrieved implants had been resterilized by steam prior to implantation and the analysis showed that it had the greatest degree of surface degradation.

The Department has consulted with the ceramic component suppliers in Europe regarding the zirconia ceramic heads currently supplied to the UK. There is general agreement that if resterilization is considered necessary then steam sterilization should not be used.

The specific instructions on resterilization provided by some orthopaedic manufacturers must be followed explicitly to ensure patient safety.

7.4 Safety Notice SAN(NI)96/32 July 1996

Polyurethane coated breast implants: continued implantation contrary to earlier advice

Summary

The Department has been informed by the National Breast Implant Registry of two instances of the implantation of polyurethane coated breast implants in the UK during the last 12 months. Because of confidentiality requirements, the Department has no details of the implanting centres. This implantation is contrary to the advice given by the Department in 1994 (SAB(94)39). In order to prevent recurrence, the advice that polyurethane coated breast implants should **not** be implanted is being restated.

Additionally these cases raise concerns over stock control and implantation of old stock since supply of polyurethane coated breast implants to UK hospitals ceased either in April 1991 (for Medical Engineering Corporation/Surgitek implants) or November 1993 (for Polytech and PIP implants) and remaining product was recalled in 1994.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include directors of plastic surgical units involved in breast reconstruction, plastic surgeons and all surgeons involved in breast reconstruction, all theatres and theatre staff, safety liaison officers and Supplies Departments.

Polyurethane coated breast implants should not be implanted.

Products involved are:

- Polytech Micro Polyurethane Structured (MPS) implants - product codes "MP" and "MPS", supplied in the UK up to November 1993
- Poly Implant Protheses (PIP) implants, supplied in the UK by Cloverleaf up to November 1993
- Medical Engineering Corporation/Surgitek Mème and Replicon implants, supplied in the UK by Cloverleaf up to April 1991

Stocks should be checked and any remaining product should be returned to the supplier.

Explantation of previously implanted devices is not routinely indicated.

Background

Department advice in 1994

The concerns over the degradation of the polyurethane (polyesterurethane) used in the manufacture of these implants was referred to the Department of Health's Committee on Carcinogenicity (COC) in 1991 and 1994. Their conclusions were published in the 1991 and 1994 Annual Reports of the Committees on Toxicity, Mutagenicity, Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (HMSO ISBN 0 11 321529 0 and ISBN 0 11 321912 1 respectively). There has been no subsequent evidence to alter these conclusions or justify reconsideration by COC.

The polyurethane used in the manufacture of breast implants is based on a polyesterurethane. Degradation of this material may lead to the release of small amounts of the probable carcinogen, 2-4-toluenediamine (2,4-TDA). Other polyurethanes used in medical devices are based on polyetherurethanes, which are made from different chemical precursors.

In September 1994, the Department issued a Safety Action Bulletin (SAB(94)39) based on the COC conclusions which included the following advice:

Polyurethane coated breast implants pose an unquantifiable (but probably low) carcinogenic risk. Since suitable alternative implants are available, these devices should not be implanted.

The integrity of the silicone shell of the implants is unaffected by the breakdown of the polyurethane foam coating.

The available data show that the amount of 2,4-TDA released decreases with time but suggest that the majority of the exposure occurs during the first 3-4 years post-implantation. There are insufficient data to quantify the rate of degradation with certainty. Since Surgitek implants were withdrawn in 1991, it is unlikely that explantation of these prostheses will significantly reduce exposure to 2,4-TDA. Although unquantifiable, the risk from leaving polyurethane breast prostheses implanted since 1991 *in situ*, is likely to be low when balanced against the small risks associated with explantation. Any decision to explant must remain a matter of clinical judgement, taking into account the wishes and condition of the patient.

7.5 Safety Notice SAN(NI)96/43 October 1996

Howmedica International Inc: polyethylene wear of the bearing surface of the 7mm resurfacing tibial components of the PCA primary knee prostheses

Summary

The Department has received eight reports of early clinical failure of the bearing surfaces of the 7mm PCA tibial resurfacing component due to polyethylene wear. This necessitated early revision after 1.5 to 4 years of implantation.

Regular medical review of patients with these implants should be considered, particularly where implants are malaligned or knee laxity is present.

Action

The following information should be brought to the attention of all who need to know or be aware of it. This will include directors of orthopaedic and surgical units, orthopaedic surgeons and safety liaison officers.

Orthopaedic surgeons may wish to consider regular medical and radiological review of patients who have been implanted with the knee tibial implants listed below, particularly and where implants are malaligned or knee laxity is present.

All batches of the following products are implicated:

Catalogue Nos.

6638 - 1 - 207	Small	7mm Left	Resurfacing tibial component
6638 - 3 - 207	Medium	7 mm Left	Resurfacing tibial component
6638 - 5 - 207	Large	7 mm Left	Resurfacing tibial component
6638 - 1 - 607	Small	7 mm Right	Resurfacing tibial component
6638 - 3 - 607	Medium	7 mm Right	Resurfacing tibial component
6638 - 5 - 607	Large	7 mm Right	Resurfacing tibial component

Background

The PCA knee system was first made available in 1981 and was phased out during 1992. The resurfacing tibial component consists of a pre-assembled Ultra High Molecular Weight Polyethylene (UHMWPE) bearing surface and a case Co - Cr - Mo alloy tray. The component was available in a range of sizes (small, medium and large) and the thickness of the complete tibial component ranged from 7 to 16 mm. The 7 mm component had a UHMWPE thickness of around 5 mm at the thinnest point. The company has estimated that around 1475 units of the 7 mm resurfacing tibial components were marketed in the UK.

There have been several published reports of early clinical failure of PCA knee tibial components (See the Bibliography).

These clinical failures have been attributed to excessive wear of the UHMWPE bearing surface and the associated factors contributing to this wear are considered by the authors of the cited papers to include non-conformity of the femoro - tibial bearing surfaces, inadequate thickness of UHMWPE and the surface finishing of the UHMWPE bearing surface by "hot pressing".

The Department has received eight reports from a single centre of early clinical failure of 7 mm PCA tibial resurfacing components due to polyethylene wear. Independent investigations of these retrieved implants on behalf of MDA confirmed the above findings regarding the contributory factors to the excessive wear. Additionally misalignment was in some cases also considered to be a contributory factor.

In late 1992 the PCA knee system was phased out by the Company and replaced by the Duracon system. The Duracon knee includes tibial components of 9 to 25 mm thickness, and femoro-tibial bearing surfaces are more conforming than those in the PCA system and surface finishing of UHMWPE by hot processing is not used. To date, the MDA has received no reports of early clinical failure or Duracon knees.

Bibliography

Selectively these include:

- Investigation of Early Surface Delamination Observed in Retrieved Heat Pressed Tibial Inserts, Bloebaum et al, Clinical Orthopaedics and Related research, No 269, August 1991.
- Polyethylene Delamination in the PCA Total Knee, Tulp N J A, Acta Orthop Scand, Vol 63 (3), 1992.
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- Catastrophic Peri Implant Bone Loss Caused by Polyethylene and Metallic Wear in Total Knees, Gustafson et al, Journal of Long Term Effects of Medical Implants, Vol 3 (2), 1993.
- Analysis of the Failure of 122 Polyethylene Inserts from Uncemented Tibial Knee Components, Collier et al, Clinical Orthopaedics and Related Research, Number 273, December 1991.

APPENDIX

Notices by title

Hazard Notices

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DISTRIBUTION

This Device Bulletin should be brought to the attention of managers and staff in all hospitals, healthcare establishments, the community and others who use medical devices. This includes: Risk Managers, Health and Safety Officers, Medical Engineering, Medical and Nursing Directorate Managers, General Practitioners, Dental Practitioners, Pathology Laboratory Managers and staff responsible for medical equipment used in the community.

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