MHRA

Medicines and Healthcare products Regulatory Agency

Safeguarding public health

Medical Device **ALERT**

Ref. MDA/2003/037
Issued: 27 October 2003

For:

IMMEDIATE ACTION	
ACTION	
UPDATE	✓
INFORMATION REQUEST	

	Further Information
DEVICE: Electrosurgical (diathermy) accessories.	*
PROBLEM: Malfunction and failure during use.	
ACTION BY: All staff involved in the use, management or processing of electrosurgical accessories.	*
ACTION: The above mentioned staff should be aware of the content of this Alert. Managers should ensure that procedures are in place to check all electrosurgical accessories regularly, to keep a record of their performance and to store them appropriately.	*
DISTRIBUTED to: NHS Trusts (England) – Chief Executives National Care Standards Commission – Headquarters	*
CONTACTS: Details of MHRA contacts. Change of address or removal from address list for services registered under the Care Standards Act 2000.	*
FEEDBACK REQUIREMENTS: None.	

* **Further information supplied in the following pages.**

The full text of this notice is on our website: **http://www.mhra.gov.uk**

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DEVICE:

Electrosurgical accessories such as monopolar and bipolar leads, footswitches, handpieces, electrodes and forceps.

ACTION BY:

All staff involved in the use, management or processing of electrosurgical accessories in a hospital, clinic or day surgery setting. This will include operating room staff, ODA's, EBME, Clinical Engineering and Medical Physics Departments, Hospital Sterile Supplies Units.

ACTION:

All staff involved in the use, management or processing of electrosurgical accessories should be made aware of the content of this Alert.
Those responsible for management of electrosurgical accessories should ensure that procedures are in place to check all reusable electrosurgical accessories regularly, to keep a record of their use and to store them appropriately. Supplementary information is provided as an Appendix to this Alert.

INSPECTION:

- Check electrosurgical cables to ensure suitability for continued use.
- Inspect footswitch assemblies for possible fluid ingress in the footswitch mechanism.
- Examine insulated instruments such as forceps and graspers for any flaws in their insulation.
- If it is necessary to perform checks beyond those recommended by the manufacturer, these should be restricted to visual inspection for damage and gentle manipulation to detect breakages.

RECORDS:

- Establish a system for determining how long a particular accessory has been in use; the age and frequency of use of the accessory should be known.
- All reusable items which need to undergo repeated sterilisation cycles should be managed with a system that provides the means of establishing the number of sterilisation cycles.
- These records provide the evidence necessary to support a structured replacement programme for accessories.

STORAGE:

- Ensure that electrosurgical cables intended for regular use are stored in places where there is the least likelihood of damage, either mechanical or otherwise.
- Ensure that footswitch assemblies are not stored hanging up, as the full weight of the footswitch can cause excessive strain on the cable anchorage points and connectors.
- Carefully store insulated instruments to avoid damage to the insulation and to the mechanism of these products.
- Withdraw accessories from storage in a controlled manner, on a first-in-first-out basis.

Ask the supplier of your reusable accessories to provide you with details concerning the storage and life span of their products and any recommended maintenance. Any items which have exceeded the number of recommended sterilisation cycles or show suspect performance should be removed from use.

DISTRIBUTION:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution by:

NATIONAL CARE STANDARDS COMMISSION to:

- Headquarters (for onward distribution)
- Hospitals in the independent sector

DISTRIBUTION (continued):

TRUSTS to:

- Liaison officers (for onward distribution)
- Directors of anaesthetics
- Medical directors
- Nursing executive directors
- Theatre managers
- Adult & paediatric intensive care units
- Special care baby units
- Accident & emergency departments
- Health & safety officers
- Risk managers
- Clinical governance leads
- Trust leads for medical device management controls assurance standard
- Maternity units
- CSSD/HSSU
- EBME, clinical engineering and medical physics departments
- Outpatient departments
- ODAs/ODPs

CONTACTS:

Enquiries to the MHRA should quote reference number **2003/007/029/061/038** and be addressed to:

Mr R Glover or Dr C McNie
Medicines & Healthcare products Regulatory Agency
Hannibal House
Elephant and Castle
London SE1 6TQ

Tel: 020 7972 8245 / 8219
Fax: 020 7972 8113

E-mail: Richard.Glover@mhra.gsi.gov.uk
Catriona.McNie@mhra.gsi.gov.uk

Change of address or removal from list for services registered under the Care Standards Act 2000.

NCSC Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0191 233 3556

E-mail: enquiries@ncsc.gsi.gov.uk

APPENDIX

BACKGROUND and INTRODUCTION

Following publication of MDA SN 9815 concerning electrosurgery (diathermy) accessories in April 1998, MHRA (formerly MDA) have had numerous enquiries concerning testing of insulation and of cable integrity. In particular we have been asked about the merits and suitability of commercial test equipment, which is marketed for this purpose. This Alert replaces MDA SN9815.

A number of incidents have been reported to MHRA in which cables and other accessories have failed during use, stressing the need for traceability of electrosurgical accessories. In many of these cases the common factors were lack of inspections or the absence of records concerning:

- the types of checks carried out and the results obtained
- the age of the accessory and
- the number of sterilisation cycles sustained by the accessory (the incidents show a positive link between number of cycles and failure rate).

Most of the defects mentioned arise where faulty items are either repeatedly not detected or are not withdrawn when it is obvious to the naked eye that they are unsuitable for continued use. The best means of assuring that any system for managing equipment works is to ensure that all concerned parties are in constructive open communication.

The list of action points given in this Alert address a range of problems and devices and not all of the proposed actions are appropriate for all devices. Choice of solutions and their implementation will depend on risk analysis and local circumstances and will need to be tempered with a measure of common sense. As an example, a lead might be specified as suitable for five years or 2000 operations but this is irrelevant if it is unintentionally cut in two on its first trip into the operating theatres.

PRACTICAL ADVICE

Summary

We recommend that if it is necessary to perform checks beyond those recommended by the manufacturer, these should be restricted to visual inspection for damage and gentle manipulation to detect breakages. We do not generally recommended electrical continuity testers since they operate at low power and may accept a cable with only 5 or 6 strands intact. Connecting such a cable to an electrosurgical generator will almost certainly result in a flash and a bang! Finally, records should be available.

Insulation tests

Insulation test equipment is commercially available and some models apply a test voltage which is considerably beyond conditions likely to be encountered in practice. Users should not assume that this higher test level is necessary. Instruments that demonstrate no operational problems may break down when tested with such devices. Although devices which pass such tests are not likely to be subject to breakdown by this mechanism in practice, they may suffer electrical breakdown due to other mechanisms such as surface tracking*. We do not recommend that cables be tested with such devices.

APPENDIX

In the case of third party electrosurgical accessories, there is no standard specification for the insulation and, without specifications quoted by the manufacturer of the generator, it remains for the purchaser to determine local requirements.

Cable breakage

The majority of faults with reusable electrosurgical cables arise from usage and relate to breakage of the conductor core rather than insulation faults. They are made to be flexible and to carry the required currents; this normally means that they have several hundred fine strands within the cable. With use these strands begin to break where they suffer the most mechanical flexing. The point of entry of a cable into its connector is generally the weakest point and you can detect the gradual breakage by gently flexing the cable.

The break is usually within a few centimetres of the connector at either end of the cable as this is the area of maximum stress on the cable. Faults most commonly occur with resectoscope cables used in TURP (prostate) procedures. This is perhaps the most stressful test of any electrosurgical accessory as it uses the highest power settings for the longest duration. This can be prevented by regularly checking cables for damage and monitoring their use (use exposes a cable to flexing and therefore gradually weakens the cable).

Records

Records need not always be exact or detailed, but it should be possible to estimate approximate data where necessary. Many devices are adequately traceable through association with specific procedure trays, etc (e.g., we have two of these devices, purchased together four years ago and they are normally used in three sessions a week: giving roughly 4 x 3 x 50 = 600 uses between two devices).

Visual examination

Prior to sterilization, visual examination (assisted by a good magnifying glass where appropriate) should be used to detect damaged insulation (fine cracks, punctures, wear, burns and other signs of damage and/or abuse). Cable faults resulting from fatigue can be detected by gently flexing the cable near the connector and again at a less vulnerable position along its length.

Prior to use in operating theatres, any damage is likely to be of a gross nature arising from trapping between trays, dropping, etc. Such damage can be seen in a quick visual examination without magnification, immediately prior to use (e.g. during setup).

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* “Surface tracking” is a means of insulation breakdown, which is especially relevant to laparoscopic and endoscopic accessories. When dissecting tissues with a laparoscopic hook electrode for example there will be a point at which the tissue is dissected and the electrode tip is still activated but no longer in contact with tissue. In this situation current may “track” along any conductive fluids on the surface of the electrode insulation until it reaches other tissues (such as liver in cholecystectomy) where it will create a local burn, raising the local tissue temperature. The electrical characteristics of some forms of insulation are very temperature dependent and will result in electrical breakdown due to such localized heating.