Safeguarding public health

MHRA

Draft for comment

Guidance on the vigilance system for CE-marked medical devices – Cardiac ablation catheters

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1 Introduction

This guidance document gives advice to manufacturers on the notification of adverse incidents involving cardiac ablation catheters (CACs) under the Medical Devices Vigilance System. It is intended to facilitate the uniform application and implementation of Medical Devices Directive 93/42/EEC and amended by 2007/47/EC [1]. It is supplementary to, and should be read in conjunction with, the European Commission Guidelines on a Medical Devices Vigilance System [2], and MHRA Directives Bulletin 3 - Guidance on the operation of the EU vigilance system in the UK [3].

This guidance sets out the Medicines and Healthcare products Regulatory Agency's (MHRA) views on the interpretation of the Medical Devices Regulations. It should not be considered to be an authoritative statement of the law in any particular case as it is intended as guidance only. Manufacturers and others should consult the legislation referred to, making their own decisions on matters affecting them in conjunction with their lawyers and other professional advisers. The MHRA does not accept liability for any errors, omissions, misleading or other statements in the guidance whether negligent or otherwise. An authoritative statement could be given only by the courts.

2 Why report?

To obtain information on device related incidents, the Medical Devices Directive [1] requires manufacturers to have procedures in place for systematic review of experience gained from device usage in the post-production phase. These review systems are particularly important in helping to ensure the continuing safety of cardiac ablation catheters, because they facilitate the early identification of performance concerns in large scale use which cannot reliably be predicted from information obtained from pre-market clinical investigations or small scale use. This is of particular importance in those patients who suffer a stroke or transient ischaemic attack (TIA) during the procedure, as identification of stroke and TIA causality during a cardiac ablation procedure is difficult and often multifactorial.

3 What should be reported?

The Medical Devices Directive [1], through the relevant national regulations [4], requires manufacturers to notify the relevant Competent Authority (the MHRA in the UK) if:

- they know of any deterioration, or malfunction, of a cardiac ablation catheter, or any inadequacy in the instructions for use which has led, or might lead, to a serious deterioration in the state of health. This would include circumstances where:

  > a cardiac ablation catheter related problem results in a clinically relevant increase in the duration of a surgical procedure, as defined by the physician

  > the cause of the cardiac ablation catheter related incident is not well defined, or involves a number of aetiological factors, and the manufacturer is unable to obtain further clarification within the reporting timescale.

- the cardiac ablation catheter has been subject to a Field Safety Corrective Action [2].

Many adverse incidents associated with cardiac ablation catheters will be reportable under the Vigilance System. It is the manufacturer's responsibility to judge each incident on its own merit, and to ensure compliance with the statutory reporting requirements contained within the relevant national regulations [4] implementing the Medical Devices Directive [1]. Use errors resulting in serious injury and not falling into any identified category should be reported in line with the Medical Devices Vigilance System [2]. The following examples are for illustrative purposes only and do not constitute an exhaustive list:

- stroke within 24 hours of the procedure
- myocardial infarction within 24 hours of the procedure
- transient ischaemic attack within 24 hours of the procedure
- pulmonary embolism within 24 hours of the procedure
- coagulum appearance on the catheter tip
- excessive tip charring as defined by the operating surgeon
- unexplained death or serious injury
- phrenic nerve paralysis
- ablation catheter withdrawal issues
- ablation catheter tip fracture
- incidents relating to accessories or equipment failure
- ablation energy delivery problems.

4 Periodic summary reporting

Some adverse incidents are appropriate for periodic summary reporting [2]. Details of the timing and content of periodic summary reports should be arranged on an individual basis with the Competent Authority. The following are examples of adverse incidents which may be considered for period summary reporting:

- angina exacerbation
- cardiac pacing issues.

5 Adverse incident trending

Some adverse incidents are expected and foreseeable, and as a result may be considered not routinely reportable. These must all be clearly identified in the manufacturer’s labelling, clinically well recognised and quantifiably predictable, well documented in the device master record with an appropriate risk assessment, and clinically acceptable in terms of individual patient benefit. All such incidents should, however, be subject to trend analysis as part of the manufacturer’s wider post-market surveillance process. The expected prevalence or rate of such events should be specified, and if an adverse trend emerges, this should trigger a vigilance report by the manufacturer to the relevant Competent Authority. Incidents which are generally only reportable if an adverse trend is identified may include:

- strokes, TIAs, pulmonary emboli and myocardial infarctions after 24 hours, but within a month.

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6 References

1. Council Directive 93/42/EEC concerning Medical Devices, OJ L169 of 12 July 1993, as amended by Directive 2007/47/EC.

2. The European Commission Guidelines on a Medical Device Vigilance System, MEDDEV 2.12-1 rev 6, December 2009.

3. Directives Bulletin 3 - Guidance on the operation of the EU vigilance system in the UK.
http://www.mhra.gov.uk/Publications/Regulatoryguidance/Devices/DirectivesBulletins/CON2033888

4. Medical Devices Regulation 2002 No 618 and Medical Devices (Amendment) Regulations 2008 No 2936.

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