Guidance on the vigilance system for CE-marked medical devices

DSVG 03

Cardiac Implantable Electronic Devices (CIED)

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Contents

1. Introduction

This document provides guidance for manufacturers of **Cardiac Implantable Electronic Devices**. It outlines specific scenarios that should be considered when determining if an incident is reportable. This document should be read in conjunction with DSVG00: Introduction to Device Specific Vigilance Guidance.

The aim of this guidance is to complement the requirements of the Active Implantable Medical Devices Directive [1] and the MEDDEV [2] and should be read in conjunction with the aforementioned. Device specific guidance does not replace or extend these requirements.

2. What Incidents Should Be Reported

The following table details **Cardiac Implantable Electronic Devices** examples indicating what should be reported as device performance problems that caused or contributed to the incident. The examples are for illustrative purposes only and do not constitute an exhaustive list:

Guidance for manufacturers on reporting device-specific incidents under the European vigilance system

To be read in conjunction with the European Commission's guidelines on a medical devices vigilance system MEDDEV 2.12/1

Cardiac implantable electronic devices and their leads

Report as individual incidents (in line with MEDDEV timescales)
Clinical / Symptomatic • Death*** • Tamponade due to cardiac perforation, pneumothorax, bleeding • Prolonged asystole*** • Life-threatening arrhythmia requiring resuscitation*** **Device** • Undersensing by ICD/lead - failure to deliver programmed defibrillation/ anti-tachycardia pacing therapy • Loss of capture/ stimulation post implant not resolved by reprogramming or repositioning (to address a threshold rise) • Inability to deliver programmed high voltage therapy • Oversensing: by ICD/lead – causing inappropriate shock or anti-tachycardia pacing unless evidence exists that it is due to electromagnetic interference • Loss of output (other than normal battery depletion) • Lead impedance** rise due to suspected conductor fracture • Delivery system failure with the potential to lead to a serious injury e.g. leadless device • Dislodgement of leadless device post implant • Programmer problem with the potential to cause serious injuries

Can be included in periodic summary reports (PSR)*	
Clinical / Symptomatic	**Periodicity**
• Pericardial effusion due to pericardial and/or myocardial perforation (without tamponade)	3 monthly
Device	
• Pacing: undersensing (risk of competitive pacing) not resolved by reprogramming • Pacing: oversensing/ noise suspected to be related to a lead malfunction • Premature/unexpected battery depletion • Lead impedance** drop due to suspected insulation failure	3 monthly
• Lead – pulse generator disconnection or set screw problem which leads to re-opening of the pocket • Reversion to back-up VVI when not designed to do so (ventricle paced, ventricle sensed, pacing inhibited) • Persistent telemetry problems in-clinic (interrogation or programming) • Remote monitoring issues (software or device related)	6 monthly

Report at the time of a statically significant increase in the frequency or severity of incidents****
Clinical / Symptomatic • Pocket or other device-related infection • Cerebrovascular accident (stroke and transient ischemic attack) • Other thromboembolic complications **Device** • Electrode displacement / dislodgement • Programmer problem without the potential to cause serious injuries • All set screw/connection problems irrespective of patient impact • Loss of capture/ stimulation post implant resolved by repositioning (to address a threshold rise)

*** If you can't use periodic summary report (PSR), then report these events individually**
**** Pacing impedance is typically considered abnormal if a measurement is <200 Ω or >1000-3000 Ω (depending on the lead model). Defibrillation impedance is typically considered abnormal if a measurement is < 20 Ω or > 200 Ω. (based on lead model and measurement range of the device)**
***** Unless information or evaluation of device indicates not device related**
****** Within a Trend Report Manufacturers may choose to include additional events associated with the same problem which have been reported as incidents, to explain their conclusion that a statistically significant increase has been identified**

This guidance is limited to devices used to manage cardiac rhythms known as cardiac implanted electronic devices (CIED), including pacemakers, ICD and CRT. Cardiac assist devices such as LVADs and BiVADs are not included.

3. Clinical Reference Guidelines

Clinical reference guidelines for a specific device may be of use to manufacturers when identifying incident examples and complications.

Current clinical guidelines for CIED procedures, expert consensus statements and current analysis of complications can be found on the European Society of Cardiology's web-site.

4. Active Implantable Medical Device Directives References

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices OJ No L 189 of 20 July 1990 last amended by Directive 2007/47/EC.

2. The European Commission Guidelines on a Medical Devices Vigilance System, MEDDEV 2.12-1 rev 8, January 2013