Guidance on the vigilance system for CE-marked medical devices

DSVG 01
Devices for Cardiac Ablation

July 2016

Contents

1. Introduction

This document provides guidance for manufacturers of **Devices for Cardiac Ablation**. 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 Medical Devices Directives [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 **Devices for Cardiac Ablation** examples indicating what should be reported as device performance problems that caused or contributed to the incident. The list is for illustrative purposes only and does not constitute an exhaustive list:

Guidance for manufacturers on reporting device-specific adverse 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

Title: Device for Cardiac Ablation*

Report as individual incidents
(in line with MEDDEV timescales)

Clinical / Symptomatic

- device may have contributed to death or serious deterioration in health and link to a possible device malfunction unknown within reporting timeframes.

Device

- ablation catheter introduction or withdrawal issues
- mechanical problem with ablation catheter (e.g. tip fracture, entrapment of multipolar ablation catheters)
- incidents relating to ablation accessories or equipment failure
- ablation energy delivery problems
- excessive coagulum appearance on the ablation catheter electrode or distal shaft of the catheter

Can be included in periodic summary reports (PSR)**

	Periodicity
• post FSCA adverse incidents	To be agreed

Report at the time the adverse trend is identified

- All reportable adverse incidents***

Clinical / Symptomatic

- stroke with an onset of symptoms within 72 hours of the procedure
- myocardial infarction with an onset of symptoms within 72 hours of the procedure
- transient ischaemic attack with an onset of symptoms within 72 hours of the procedure
- pulmonary embolism with an onset of symptoms within 72 hours of the procedure
- cardiac perforation / pericardial effusion / tamponade
- unexplained death or serious injury

- excessive ablation electrode charring as defined by the operating clinician or user
- saline or medium leak (e.g. cryo fluid)
- cardiac ablation system parameter anomalies (e.g. temperature or impedance value, alarm or display warning malfunction) which result in patient injury
- failure to deliver pacing energy

- phrenic nerve paralysis with an onset of symptoms within 72 hours of the procedure
- collateral tissue damage e.g. damage to oesophagus or other non-intended tissue damage following ablation
- angina exacerbation with an onset of symptoms within 72 hours of the procedure
- cardiac pacing issues encountered during the procedure, which did not require intervention to mitigate serious injury or death

Device

- coagulum (non-excessive) appearance on the ablation catheter electrode or distal shaft of the catheter ablation electrode charring (non-excessive)
- ablation popping

***If in an incident appears to meet criteria contained in more than one column, ensure it is included in submissions under each reporting format, even if this results in duplication of reporting for that incident.**

**** If you can't use PSR, then report these events individually.**

***** Until the new MIR form, which includes similar incident data, is adopted, trend reports should be submitted for reportable events, in line with the requirements of MEDDEV 2.12/1.**

5. 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 cardiac therapeutic procedures, expert consensus statements and current analysis of complications can be found on the European Society of Cardiology's web-site.

6. Medical Device Directives References

1**.** Council Directive 93/42/EEC concerning Medical Devices, OJ L169 of 12 July 1993 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