MDCG 2024-1-1

Guidance on the vigilance system for CE-marked devices

DSVG 01

Devices for Cardiac Ablation

January 2024

Contents

1. Introduction

The aim of this Device Specific Vigilance Guidance (DSVG) is to harmonize vigilance reporting and provide guidance for manufacturers of **Devices for Cardiac Ablation**.
It provides further clarification for vigilance reporting of **Devices for Cardiac Ablation** to the relevant Competent Authority and should be read in conjunction with the requirements of Regulation (EU) 2017/745 on medical devices (MDR) [1].
This DSVG does not replace or extend any of those requirements.

This document outlines the way to report incidents and serious incidents, defined in Article 2(64) and (65) MDR, in accordance with Articles 87 and 88 MDR, which occurred with **Devices for Cardiac Ablation** to the relevant Competent Authority.

2. What should be reported

It is the manufacturer's responsibility to judge each event on its own merit and to ensure compliance with the statutory reporting requirements contained within the MDR [1].

- **Individual serious incident**

In accordance with Article 87 MDR [1] manufacturers shall report serious incidents to the relevant Competent Authority. **Serious incidents** are defined in Article 2(65) MDR.

This includes circumstances where the manufacturer is uncertain whether the incident that occurred with a specific device is reportable or needs time to obtain clarification about the root cause of the incident, in accordance with Article 87(6) and (7) MDR.

The notification to the relevant Competent Authority should be reported within the timeframes referred to in Article 87(2) to (5) MDR.

For further information and clarification on what constitutes a serious incident and for details on how to apply the reporting timelines of the MDR, please refer to MDCG 2023-3[1] "*Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices"* [2].

- **Periodic Summary Reporting**

A "**Periodic Summary Report**" (PSR) is an alternative reporting regime by which the manufacturer, in agreement with the respective national Competent Authority that is coordinating the periodic summary reporting (and in consultation with the Competent Authorities referred to in Article 92(8)(a) MDR), can report similar serious incidents with the same device or device type in a consolidated way.

This is possible when similar serious incidents involving the same specific device or device type occur and for which the root cause has been identified or a field safety corrective action has been implemented or where the serious incidents are common and well documented, as defined in Article 87(9) MDR.

The format, content and frequency of periodic summary reports should be agreed with

[1] MDCG 2023-3 guidance is under revision to include IVDR aspects. Please refer to the updated version when available at the following link: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#guidance.

the Coordinating Competent Authority (in consultation with the Competent Authorities participating in the Periodic Summary Reporting) (Article 87(9) MDR).

Until EUDAMED becomes fully functional, Competent Authorities, economic operators and other relevant parties should follow MDCG 2021-1 Rev. 1 *"Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional*" [3] (as required under the MDR).

- **Trend Reporting**

The requirements for **trend reporting** are outlined in Article 88 MDR [1].

In accordance with the **MDR**, the manufacturer should report to a Competent Authority any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. Trends should be identified by the manufacturer as they can be indicative of a change in the risk-benefit ratio.

For further information and clarification on what constitute incidents and undesirable side-effects please refer to MDCG 2023-3 "*Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices*" [2].

3. DSVG 01 examples

The following table details **Devices for Cardiac Ablation** examples indicating what should be reported as device-related problems that caused or contributed to the incidents or serious incidents.

The list is for illustrative purposes only and does not constitute an exhaustive list:

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

To be read in conjunction with the MDR

Title: Devices for Cardiac Ablation

Report as individual serious incidents

Serious incident: Art. 2(65) and Art. 87 MDR.

Reporting timelines: by 15, 10 or 2 days from the Manufacturer's awareness in accordance with Art. 87(3) to (5) MDR.

- device may have contributed to death or serious deterioration in health and link to a possible device malfunction unknown within reporting timeframes **E060106**

Device (IMDRF Annex A codes*)

- ablation catheter introduction orwithdrawal issues **A150206 / A150207 / A0406 / A1502 / A150204 / A1702 / A040601 / A040609**
- mechanical problem with ablation catheter (e.g. tip fracture, entrapment of multipolar ablation catheters) **A0413 / A040101 / A150208 / A1503 / A0406 / A0411 / A0501 / A0404 / A0401 / A040609 / A05 / A041001**
- incidents relating to ablation accessories or equipment failure **A12**
- ablation energy delivery problems **A1003 / A1004 / A072102 / A090807 / A0709 / A072202 / A0722 / A090402**
- excessive coagulum appearance on the ablation catheter electrode or distal shaft of the catheter **A180103 / A0702**
- excessive ablation electrode charring as defined by the operating clinician oruser-**A180103**
- saline or medium leak (e.g. cryo fluid) **A050401**
- cardiac ablation system parameter anomalies (e.g. temperature or impedance value, alarm or display warning malfunction) which result inpatient injury **A090807 / A0908 / A090808 / A070908 / A090205**
- failure to deliver pacing energy **A071204 / A0712**

Can be included in Periodic Summary Reports (PSRs)**

- Post FSCA serious incidents

Periodicity

To be agreed

Report at the time the trend is identified

Incidents (Art. 2(64) and Art. 88 MDR) and expected undesirable side-effects***

- stroke with an onset of symptoms within72 hours of the procedure **E0133**
- myocardial infarction with an onset ofsymptoms within 72 hours of the procedure **E061202**
- transient ischaemic attack with an onsetof symptoms within 72 hours of the procedure **E0137**
- pulmonary embolism with an onset ofsymptoms within 72 hours of the procedure **E050303**
- cardiac perforation / pericardial effusion/ tamponade **E0604 / E0605 / E0619**
- unexplained death or serious injury **E0623**
- phrenic nerve paralysis with an onset ofsymptoms within 72 hours of the procedure **E0123 / E012202**
- collateral tissue damage e.g. damage to esophagus or other non-intended tissue damage following ablation **E0621 / E062102**
- angina exacerbation with an onset ofsymptoms within 72 hours of the procedure **E061201 / E233001**
- cardiac pacing issues encountered during the procedure, which did not require intervention to mitigate seriousinjury or death **E060104 / E060109 / E0618 / E0601 / E060101 / E060102**

Device (IMDRF Annex A codes*)

- coagulum (non-excessive) appearance on the ablation catheter electrode or distal shaft of the catheter ablation electrode charring (non-excessive) **A180103**

*** The IMDRF Annexes codes associated with each text description are included as guides (please see the Section 5).**

**** If you can't use PSR, then report these serious incidents individually, using MIR Form. The format, content and frequency of PSRs should be arranged with the Coordinating Competent Authority.**

***** Any statistically significant increase in the frequency or severity of incidents and expected undesirable side-effects shall be reported by the manufacturer in accordance with Article 88(1) MDR.**

4. Clinical References and Clinical Guidelines

Clinical references or current clinical guidelines for **Cardiac Ablation devices** may be used by manufacturers in order to identify 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 website (https://www.escardio.org/).

5. IMDRF Terminologies for Categorised Adverse Event Reporting

The text descriptions of Medical device problems (IMDRF Annex A) and Health effects - Clinical signs and symptoms (IMDRF Annex E) in the table are examples of what should be reported and refer to the IMDRF Annex A and E release No. 2023.

Please note that manufacturers should consult the most recent version of the IMDRF adverse event code.

The following link is provided to facilitate consultation:
https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes.

6. References

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[2] MDCG 2023-3 "*Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices*". Link: https://health.ec.europa.eu/system/files/2023-02/mdcg_2023-3_en_0.pdf.

[3] MDCG 2021-1 Rev. 1 "*Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional*". Link: https://health.ec.europa.eu/system/files/2021-05/2021-1_guidance-administrative-practices_en_0.pdf.