Guidance on the vigilance system for CE-marked medical devices

DSVG 02

Coronary Stents and associated delivery systems

September 2015

Contents

1. Introduction

This document provides guidance for manufacturers of **Coronary Stents**. 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 **Coronary Stent** 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 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

Coronary stents and associated delivery systems*

Report as individual incidents
(in line with MEDDEV timescales)

Clinical / Symptomatic

- Death that is probably or possibly device related
- MI or heart failure that is probably or possibly device related
- Acute coronary arterial perforation / dissection leading to haemopericardium / pericardial effusion or tamponade
- Cardiogenic shock

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

Clinical / Symptomatic	Periodicity
• Adverse reaction associated with the stent material (including, drug or polymer carrier) and / or delivery system materials	12 monthly
• Stent/target vessel thrombosis (Thrombotic occlusion / embolism) or: In-stent re-stenosis or: target vessel or lesion revascularisation	3 monthly
• All CVA (Stroke & TIA) within 12 months of PCI procedure. Listing acute, sub-acute and late strokes separately. This should be separated out by haemorrhagic or ischemic stroke.	3 monthly

Report at the time the adverse trend is identified

- All reportable adverse incidents***

Clinical / Symptomatic

- Side branch occlusion
- Distal emboli (tissue, thrombotic / thrombus, plaque)
- Acute peripheral artery injury / perforation / dissection
- Non-fatal bleeding complications (e.g. haemorrhage), which may require transfusion
- Infection – local and / or systemic
- Peripheral vascular or nerve injury

Device

- Mechanical failure of the delivery system (e.g. fracture / breakage)
- Mechanical failure of the stent, (e.g. fracture / collapse) during or after implant
- Stent fragment migration or embolisation after implantation
- Difficulty deflating the delivery system balloon
- Other delivery system (device deployment or withdrawal) complications, resulting in actual serious injury (including significant extension to procedural time)

Device	
• In vivo stent deformation (e.g. longitudinal stent deformation)	6 monthly
• Pre / Post stent deployment dislodgement in-vivo, with or without migration (stent embolism)	6 monthly
• Difficulty advancing the stent or crossing the lesion. If known to be associated with procedural or patient factors then only report if adverse trend identified	6 monthly
• Incomplete stent apposition / expansion or excessive recoil, (despite correct adherence to IFU) that requires further intervention	6 monthly
• Other delivery system (device deployment, or withdrawal) complications, not resulting in serious injury but with the potential to do so.	6 monthly

Device

- Difficulty advancing the stent or crossing the lesion, linked to procedural or patient factor

***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.**

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

4. 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