Periodic Safety Update Report (PSUR)

This report describes product-specific post-market surveillance activity output as outlined in the Post-Market Surveillance Plan.

1. Executive Summary

Describe the main results of the current PSUR and provide background information so that the PSUR "stands alone". Executive summary should provide a clear and bold statement declaring whether the benefit risk ratio has been negatively impacted based on the information reported within the current PSUR. This statement should be added after the conclusions of the PSUR have been completed.

2. Purpose and Scope of the PSUR

This Periodic Safety Update Report (PSUR) applies to [Device Name] and summarizes the results and conclusions of the analyses of the post-market surveillance data. Furthermore, this report provides a rationale and description of any preventive and corrective actions taken.

General information
Surveillance Period:
PSUR Reference Number:
PSUR Version Number:

3. Device information

This PSUR covers:
Device name:
Device model:
Legal manufacturer
Classification:
Basic UDI:
Date of the first DoC:
Notified Body name and organization number:
Expected lifetime of device:

3.1 Intended Use

Add intended use.

3.2 Patient Population

Add patient population

3.3 Intended Medical Indication

Add intended medical indication

3.4 Contraindications

If none, state as follows: There are no known specific situations that contraindicate the use of this device.

3.5 Operating Principle

Offer a detailed overview of the device, encompassing its name, models, sizes, and components across hardware, software, and accessories. Clearly categorize the device, such as a biological artificial aortic valve, and outline its physical and chemical attributes, technical specifications, and mechanical traits. Specify sterilization methods, radioactivity considerations, and operational principles. Detail materials used, particularly those in contact with the patient, and any inclusion of medicinal substances, animal tissues, or blood components. Incorporate a visual representation, and note the device's class, global market entry, and specific product configurations. Highlight innovative features relevant to ongoing assessments and address unmet medical needs. Provide concise step-by-step application procedures, elucidate performance in different modes, and describe the device's workflow.

3.6 User Profile

Describe the typical user of the software. Some ideas could be: Qualifications, prior training (for your software), technical proficiency, time spent using the software.

3.7 User Environment Including Hardware / Software

Describe the typical use environment. What sort of devices is this running on? Does the software only run on one device or multiple devices? Is it loud and chaotic like in an emergency ward? How's the lighting? Also, add other software or hardware which is required by your device. Most commonly, apps require users to have a smartphone with a compatible operating system (iOS / Android).

3.8 Characteristics of the Population using the Device

Describe the observed usage of the device in different patient populations in comparison to the expected usage and identify the possible over-represented or under-represented patient groups.

3.9 Volume of Sales

Provide an accurate information on the number of devices sold and the possible changes on it. The data should be presented by year to year. Provide also further information on the volume of sales in respect to the various sizes, models and system components of the device.

4. Summary of PMS Activities

4.1 Feedbackback and Complaints

4.1.1 Serious incidents

Summarize all serious incidents and describe the influence on the risk management and the risk benefit evaluation.

4.1.2 Non-Serious incidents and expected undesirable side effects

Summarize all non-serious incidents and describe the influence on the risk management and the risk benefit evaluation.

4.1.3 Proactively gathered feedback

Summarize the activities and findings, any consequences on risk management and/or clinical evaluation, including any follow-up activity.

4.2 Trend identification and reporting

Summarize information on any detected trends for non-serious incidents or expected undesirable side-effects. Summarize the activities and findings, including the reporting to the regulatory authority and any required follow-up activity.

4.3 Technical & Specialist Literature

Summarize information coming from specialist or technical literature, such as regulations, directives, guidance document updates, common specifications, product standards, specialist journals, etc.

4.4 Information about Similar Devices

Summarize information coming from publicly available sources and channels for complaints or other experience databases on equivalent/similar devices (such as FDA MAUDE, MHRA, Swissmedic, Implant Registries, etc.).

4.5 Summary of FSCA Documentation

Summarize the information on field safety and corrective actions.

5. Main findings from PMCF Activities

5.1 List of PMCF Studies

Summaries all ongoing and plannend PMCF studies.

5.2 Systematic Literature Research

Reference the CER or provide a summary of the literature search.

6. Information from previous PSURs

Information from the previous PSUR / PMSR (if available) to identify pending actions during that reporting periods.

7. Change of the State of the Art

Describe whether there is any change of the device state of the art when compared with the evaluation from the current Clinical Evaluation Report.

8. Risk Management & Benefit-Risk Assessment

Potential failure modes (hazards) and harms related to use of the Device Name/Group have been identified, assessed and controlled during development according to EN ISO 14971:2019. No new hazards and harms were identified as a result of the PMS activities conducted during the present review period, and no update of the risk management file has been made due to safety and performance issues.

In conclusion, the results referred to above demonstrate a continuous acceptability of the benefit-risk determination of the Device Name/Group , i.e. the risks associated with use of the device are still outweighed by the benefits of the device.

9. Required Updates to PMS Plan

Describe the plannend updates of the PMS plan.
