Summary of Safety and Clinical Performance (SSCP) in a nutshell (1/4)

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Summary of Safety and Clinical Performance under EU-MDR

Article 32

Summary of safety and clinical performance

1. For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available.

2. The summary of safety and clinical performance shall include at least the following aspects:

(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN;

(b) the intended purpose of the device and any indications, contraindications and target populations;

(c) a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device;

(d) possible diagnostic or therapeutic alternatives;

(e) reference to any harmonised standards and CS applied;

(f) the summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable effects, warnings and precautions.

3. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

- **Art. 32:** The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of a medical device.
- It is only applicable to implantable devices (IIa as well) and class III devices, other than custom-made or investigational devices
- Key role in the post-market clinical follow-up – aligned at all times with TechDoc
- For the following devices, the SSCP will have a part intended for patients:
  - ✓ implantable devices for which patients will be given implant cards
  - ✓ class III devices that are intended to be used directly by patients.
  - ✓ Devices listed in MDR Annex XVI
- **The SSCP has to be validated by the Notified Body (NB) – refer to MDCG 2019-9**
- When EUDAMED is made available, SSCPs will be publicly available

Translations to EU languages

- the SSCP should be translated into the languages accepted in the Member States where the device is envisaged to be sold similarly to IFU [Annex II (2), Art. 10, par. 11]
- Translation in English is mandatory

Healthcare Professionals

The SSCP is **NOT**
intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients. It does not replace the mandatory information on implant cards or in any other mandatory documents.

Patients and/or Lay persons

The SSCP is **NOT**
intended to give general advice on the treatment of a medical condition and/or to replace an implant card or the Instructions for Use (IFU).
Readers must encouraged to contact their healthcare professional for questions about their medical condition or the use of the device.

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Physician Section

- ❑ The information included in a SSCP **shall** be fully aligned with the technical documentation (TD) of the device including design verification/validation reports, risk management reports, Clinical Evaluation Report (CER), Post-market Surveillance (PMS), Post-market Clinical Follow-up (PMCF) plans and reports
- ❑ When writing the CER of a device requiring a SCCP, keep in mind that the latter should outline numerical comparative and normative data for risks, adverse events, etc.

> ➢ **Although the content will be practically the same, watch out for readability and language register in the section for patients or Lay persons**

Patient/Lay Person Section

- ❑ This section must be written in a way that will be accessible to lay persons, i.e. it should be easily readable and comprehended by people with a reading level of 12 years old and over.
- ❑ When preparing this section, do not assume that the reader has any formal medical education and/or prior knowledge of medical terminology and clinical research principles
  - ✓ Avoid abbreviations and acronyms that may confuse non-specialists, use short sentences and familiar words
  - ✓ If medical terms are used, be consistent: Start by giving a description of the lay term and put the medical term in brackets.
- ❑ Always evaluate the readability of the text and mind the stylistic recommendations

"The SSCP shall be objective and adequately summarise both favourable and unfavourable data"


Medical Device
Medical Device Coordination Group Document MDCG 2019-9

MDCG 2019-9

Summary of safety and clinical performance

A guide for manufacturers and notified bodies

August 2019

Summary of Safety and Clinical Performance (SSCP) in a nutshell (3/4)

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SSCP contents for users/healthcare professionals

- **Device Identification:** trade name(s), manufacturer's contact details and SRN, UDI identifier, GMDN/EMDN codes, classification & respective rationale, year of first CE mark, contact details for the Authorised Representative, identification of the validating Notified Body
- **Labelling Statements**: intended purpose, indication(s), intended population, contraindications, warnings & cautions, intended lifetime, intended clinical benefit(s)
- **Description of the device:** models, accessories, configurations, design characteristics, operating principles, device specifications including materials, expiry date, intended lifetime, packaging specifications, whether the device is for single use or multiple uses and its method of sterilisation, statements with respect to incorporation of medicinal substances, tissue(s) or cells of human or animal origin, substances or combinations of substances that are absorbed by or locally dispersed in the human body, materials containing and/or consisting of CMRs or endocrine-disrupting substances, or materials that could result in sensitisation or an allergic reaction by the patient or user
- **Description of accessories and/or devices or products that are used in combination with the device**
- **Overview of risks associated with the use of the device:** evaluation of clinical residual risks and undesirable effects other than those included in labelling statements for contraindications, discussion of risk severity, risk mitigation strategies and occurrence of hazardous situations, description of any FSCAs, FSNs, CAPAs, recalls.
- **Summary of Clinical Evaluation and PMCF: descriptive** summary of **ALL** clinical data pertinent to the device regardless of their origin, i.e data from clinical investigations prior and/or post CE-marking, data related to equivalent devices, data from literature, PMS/PMCF activities (ongoing and/or planned
    - ✓ **IN ALL CASES**, a proper qualitative and quantitative identification must be provided (e.g. study objectives, primary/secondary endpoints, eligibility, study population, summary of results etc.
- **Identification of the intended medical field:** overview of alternative treatment options and associated benefit-risk analysis
- **Suggested profile and training needs for healthcare professionals**
- **Reference to Harmonised Standards and/or Applicable Common Specifications**
- **Revision History**

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SSCP contents for patients/lay persons

- **Device Identification:** trade name(s), manufacturer's contact details, UDI identifier, year of first CE mark and explanation of why this is an important information, contact details for the Authorised Representative, identification of the validating Notified Body
- **Intended use of the device**:
  - ✓ Intended Purpose: What is the device used for?
  - ✓ Indications and Intended Patient Groups: When is the device used? (Indications) + Who is the device meant for? (Intended Patient Groups)
  - ✓ Contraindications: When should the device not be used?
- **Description of the device:** operating principles, design characteristics, models, accessories, configurations, whether the device is for single use or multiple uses and whether it is supplied sterile, statements with respect to incorporation of medicinal substances, tissue(s) or cells of human or animal origin, substances or combinations of substances that are absorbed by or locally dispersed in the human body, materials containing and/or consisting of CMRs or endocrine-disrupting substances, or materials that could result in sensitisation or an allergic reaction by the patient or user
  - ✓ Make sure you explain terms such carcinogenic, endocrine disruptor, sensitisation etc. as well as the meaning of medicinal substance in a medical device
- **Description of how the device works:** how the device is powered, operated, maintained etc. This section should include information/instructions on how the patient might use the device on its own.
- **Risks and Warnings:** an overview of risks associated with the use of the device, while ensuring that the lay person understands quantification or risks as well as steps required to reduce these risks, explanation or clinical residual risks and undesirable effects, outline of all warnings and precautions, summary of any FSCAS and/or recalls explaining what they are and how they ensure the device's continued safety
- **Summary of Clinical Evaluation and PMCF:** provide a description of available clinical evidence preferably in a chronological order explaining how clinical data provides evidence of safety for the device.
- **Possible Alternative Options:** describe the alternative therapeutic options available for the intended purpose of the device and explain how these alternatives compare to the subject device in terms of the risks and benefits
- **Suggested Training for users:** describe the experience, education and/or training of the intended user including potential mandatory training required before using the device and any required training for the continued safe use of the device