Summary of Safety and Clinical Performance

What is SSCP?

The summary of safety and clinical performance (SSCP) is a new requirement of the EU Medical Devices Regulation (EU MDR).

SSCP provides a summary of the risks and benefits of certain devices and must be provided for all Class III and implantable devices (other than custom-made or investigational devices) and will be available in EUDAMED. The IFU shall contain all that is needed to directly find the SSCP in EUDAMED.

This factsheet provides healthcare professionals (HCPs) with more information on SSCP.

Purpose of SSCP

The SSCP allows public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device.

The SSCP will be an important source of information for intended users – both HCPs and, if relevant, for patients. It is one of several means intended to fulfill the objectives of EU MDR to ensure a robust, transparent, and sustainable regulatory framework and maintain a high level of safety.

SSCP Contents

The SSCP contains easily understood and relevant information for HCPs and, when relevant, the public. This information is presented in separate sections and uses language and terms appropriate for the respective audience.

Key information captured in the SSCP includes the description and intended use of the devices in scope, associated risks and warnings, an objective summary of existing and planned clinical data, and possible diagnostic or therapeutic alternatives.

After review and approval by a Notified Body, it is the Notified Body's responsibility to upload the SSCP into EUDAMED. Prior to the EUDAMED mandatory usage date, the manufacturer makes the SSCP available upon request.

When is the SSCP Updated?

The SSCP shall be kept updated in EUDAMED. It should be reviewed and updated, as indicated, when the periodic safety update report (PSUR) and clinical evaluation report (CER) are updated. All sections of the document shall be updated as needed to ensure alignment with the most current version of the technical documentation (TD) of the device.

Accessing the SSCP

The SSCP can be obtained from the EUDAMED public website once the mandatory usage date occurs. The IFU shall contain all that is needed to find the SSCP in EUDAMED; value of the Basic UDI-DI or another metadata can be stated, provided it can be used to unambiguously search and find the intended SSCP in EUDAMED.

The official web address of the EUDAMED public website is https://ec.europa.eu/tools/eudamed.

What is EUDAMED?

EUDAMED is a secure web application used to capture and share data related to medical devices placed on the EU Market. The system is comprised of a restricted site with six interconnected modules where relevant stakeholders create content. The six modules relate to:

1. Actor Registration
2. Unique Device Identification (UDI) and Device Registration
3. Notified Bodies and Certificates
4. Clinical Investigations and Performance Studies
5. Vigilance
6. Market Surveillance

A separate public facing website is also available to provide access to a large portion of the information and strengthen confidence in the safety of medical devices available on the market.

Set up by EU Commission, EUDAMED aims to enhance overall transparency through better access to information for the public and healthcare professionals, and to enhance coordination between the different Member States in the EU.

Johnson & Johnson MEDTECH

If you have questions, please contact your local customer service team or Johnson & Johnson MedTech sales representative. Prior to EUDAMED activation, requests for SSCPs can be made through the JnJ Medical Affairs team via the Medical Information Requests (MIR) portal: Medical Information Request (MIR)

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