Summary of Safety and Clinical Performance (SSCP) requests

What is SSCP?

The Medical Device Regulation 2017/745 applicable in the European Union requires that high risk (class III) and implantable devices manufacturer's draw up a summary of safety and clinical performance (SSCP).

The SSCP is a document expected to provide public access to a summary of clinical data and other information about the safety and clinical performance of the medical device.

SSCP is not intended for giving general advice on the diagnosis and treatment of specific medical conditions, nor replacing IFU as the main document for ensuring safe use of a device, nor replacing information on implant cards or in any mandatory documents.

The SSCP is regularly updated and made available to the public via the European database on medical devices (Eudamed: https://webgate.ec.europa.eu/eudamed/landing-page#/).

However, Eudamed is not yet functional. Until notice of functionality of Eudamed has been published, and up to 6 months after publication, the SSCP shall be made available by the manufacturer to the public upon request.

How do I get the SSCP for my device?

Please reach out to your local Advanced Bionics representative for requesting the SSCP of your concerned device.

In order for Advanced Bionics to provide you the correct SSCP, please provide the device name and model number.