EASSI
European Association of the Surgical Suture Industry

Position paper
Surgical sutures in the context of medical device regulation

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Purpose and Scope

This position paper is intended to provide actors of the Medical Device Regulation (MDR)[1] with an expert's view on the status of surgical sutures, in particular related to a reasonable interpretation of clinical evidence.

Product description

Surgical sutures are the most widely used wound closure devices with a millennia of history. They serve to approximate tissue. A number of different shapes, sizes, structures, needle and thread materials are available.

Surgical sutures have been used routinely in surgical procedures in all anatomical regions of the body for several decades and with millions of applications every year. The intended users are healthcare professionals like surgeons that are qualified and familiar with the surgical techniques.

Surgical sutures have a relatively simple, common and stable design. They are not in the focus of research and clinical investigations but there are many references to sutures in scientific literature. Their use represents a well-established standard of best practice. The long-lasting market experience confirms a positive benefit-risk-ratio of surgical sutures without any concerns related to their clinical safety and performance.

Standardized requirements

Surgical sutures are based on well-established technology. Standardized requirements have been implemented long time ago in the United States Pharmacopeia (USP) and the European Pharmacopoeia (EP).

Monographs in the European Pharmacopoeia, "in particular on surgical sutures" are acknowledged by Art. 8 paragraph 2 of MDR as equivalent to harmonised standards.

The EP monographs on surgical sutures "can be applied to show compliance with certain requirements" of MDR [2, 3, 4, 5]. The specified physical properties (consistent diameter, sufficient strength/breaking load and firm needle attachment) are "essential for the effectiveness and

[1] Medical Device Regulation EU 2017/745 as amended.
[2] European Pharmacopeia. 10.1. 04/2020: 90004: sutures for human use – introduction.
[3] European Pharmacopeia 10.0. 07/2018:0324 corrected 10.0. Sutures sterile synthetic non-absorbable.
[4] European Pharmacopeia 10.0. 01/2008: 0666. Sutures, sterile synthetic absorbable monofilament
[5] European Pharmacopeia 10.0. 01/2008: 0667. Sutures, sterile synthetic absorbable braided.

the performance characteristics during use and during the functional lifetime". The requirements consider "stresses which occur during normal conditions of use" and thus can be used to demonstrate the suitability "for wound closure in accordance with usual surgical techniques" [3, 4, 5]. Thus compliance with standards demonstrates the clinical performance. Additional proof of biocompatibility, sterility and packaging integrity provided by the manufacturer support the clinical safety.

This special status of surgical sutures is considered in the MDR. Article 61 paragraph 6 of the MDR clarifies that the requirement to perform clinical investigations shall not apply to implantable devices and class III devices that are sutures. Article 18 paragraph 3 of MDR further exempts sutures from the obligations of an implant card.

Conclusion

The level of clinical evaluation must be adjusted to the risk and nature of the medical device. With their acknowledged special status, surgical sutures should be included in the scope of Article 61 (10) MDR irrespective of their risk classification and should be exempted from the requirements of clinical data. Suitable control measures are in place to appropriately mitigate the risks to health and include as crucial element the demonstration of compliance with the monographs of the European Pharmacopoeia.

EASSI – the European Association of the Surgical Suture Industry – represents the interests of European manufacturers of surgical sutures and meshes. The 20 member companies are located in the Czech Republic, France, Germany, Great Britain, Italy, Spain and Switzerland (www.eassi.eu/members).