

Silk Fibroin implantable devices: different sites, different pathways.

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Abstract

Silk Fibroin is one the most ancient materials used in medical applications, however very few devices, except sutures, are approved from FDA or have achieved CE mark.

Silk Biomaterials (SILK) is a medical technology Italian start-up established in 2014 to develop innovative technologies for medical implantable devices based on silk fibroin. Its ambition is the in-vivo regeneration of human tissues by harnessing the natural properties of silk and experimenting with the first fibroin-made grafts for tissue repair procedures. The long-term objective is to create a solid technology platform for regenerative medicine and other specific procedures (vascular grafts and ligaments reconstruction, dura mater, skin repair, etc.).

In these years SILK is working on several devices for different clinical needs and, therefore, different implantation sites. We started talks with the FDA for some of these to define the correct experimental and regulatory pathways. As a function of the clinical need, the devices have different requirements about e.g. morphology, mechanical properties, degradation rate.

Those different requirements have to be assessed with unique experimental plans according with the regulatory requests of FDA or European Notified Bodies.

Biography

Antonio Alessandrino, Chairman of the Board and Chief Technology Officer of Silk Biomaterials srl. PhD in Materials Engineering at Politecnico di Milano, Antonio is an expert in the development of silk medical implantable devices for regenerative medicine. Previously to Silk Biomaterials srl, he acted as R&D specialist in INVISTA® a company of KOCH Industries and as R&D freelance consultant working also as temporary manager for R&D and product development projects.

Since 2014, he is involved in SILK, where his responsibilities primarily include:

- Identification of opportunities and applications for the owned technologies
- Management of R&D activities
- Monitoring and scouting of technologies
- Definition of the company's IP & technology strategy

He is the inventor in several patents or patent applications related to the use of silk fibroin in medical application; he is also the author of 15 peer-reviewed articles.



Giuliano Freddi, Chief Scientific Officer. Formerly the head of the Biotechnology and Biomaterials Department of Innovhub - SSI, he has a profound knowledge in silk-based biomaterials and development of tissue engineered scaffolds. His research interests are:

biomedical utility of silk proteins for the development of tissue engineering devices and bioactive dressings; textile biotechnology, with emphasis on exploitation of enzymes for polymer and fibre processing aiming at the substitution of traditional chemical treatments with new ones based on biocatalysis. He also works on quality control and testing of raw materials, intermediates, and final products. He is involved in technical and scientific education for both technicians of the textile sector and students at all levels. He is a member of standardisation committees at national and international level and is a consultant for international organizations (World Bank, FAO). In SILK he acts also as Principal Investigator (PI) or Unit Coordinator (UC) in national and international research projects. He has about 140 publications in peer-reviewed journals and he is the author in 8 patents.

