Critical Issues in Manufacturing Active Medical Implants

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Active implantable medical devices could have high potential of being hazardous to the health of patients. This is due to their combination of the two characteristics of a) relying on a power source, and b) being at least partially introduced into the human body and being intended to stay there for extended period of time. It is thus not surprising that active implantable medical devices have to comply with a plethora of standards. Colloquially but not fully correctly this is often broadly referred as 'biocompatibility'. Biocompatibility is only one of the requirements a medical implant has to meet.
It is evident that an active medical implant should not harm the patient, i.e. all materials being in direct contact with the body should be biocompatible. It is also evident that the source of (mostly electrical) energy contained in an implant should not harm the patient by electric shock or similar. Researchers who are not so experienced in the field of active implantable medical devices often underestimate what harm the harsh environment inside the body can have on the implanted medical device. It is obvious that a failure of the implant will be very critical or even life-threatening if the patient's health relies on the proper functioning of the implant. It is thus important to protect the implant and especially the implant electronics from body fluids by encapsulating the implant. The choice of encapsulation material and technology obviously strongly depends on the purpose of the implant and the specific requirements which the implant has to fulfil. A rather well-known and commonly applicable encapsulation method is encasing the implant with a hermetically sealed housing. For example it can be made of biocompatible titanium with welding for hermetic sealing. However, this rather straight forward encapsulation method is not the method of choice if the implant has to communicate with an extracorporeal device via electromagnetic waves. In this case, depending on the frequency range used for communication, the titanium housing could significantly dampen the electromagnetic signals making a communication impossible. Using a rigid metal housing is even absolutely impossible if a mechanically bendable implant is required. Therefore, polymer coatings are applied to encapsulate the implant electronics. Such mechanically flexible/bendable implants have already been reported in the literature. Usually they consist of a flexible printed circuit board, which contains electronic components. Finally a soft coating material, e.g. silicone is applied to cover the flexible electronic circuit. Although many researchers have used this encapsulation approach during the past years, the results reported in the literature are rather frustrating when taking long-term implantability into account.

In this paper, several approaches for encapsulating medical implants will be presented. Their pros and cons will be discussed. The most critical aspects of encasing active medical implants will be highlighted.