Bioretec Orthopaedics and Traumatology Product Biocompatibility Info

From the chemical point of view medical grade poly L-lactide-co-glycolide copolymer (PLGA) used in Bioretec's orthopaedics and traumatology products do not contain components, which could negatively affect on the biocompatibility of the material. The monomers of PLGA are the L-lactic acid and glycolic acid, which are part of normal chemistry of mammalian cells. The hydrolytic degradation of PLGA copolymers, which takes place in human body, produces only those very same monomers.

The literature review on clinical use of PLGA materials highlights the good experiences gained from use of different PLGA -copolymers in different fields of surgery in bioabsorbable bone fixation devices. PLGA copolymers overcome the problems related to too fast degradation of PGA and too slow degradation of PLLA by a good compromise of the degradation properties of those two homopolymers. Because the foreign body reaction is in fact the process, which human body uses to degrade and finally absorb the material, it cannot be avoided. By using right material, proper implant design and proper surgical practice, it is possible to avoid clinical problems caused by the foreign body reaction, triggered by the degradation of the bioabsorbable implant material. The orientation techniques applied in the manufacturing processes at Bioretec increase the strength of the material, thus enable implant designs with less material comparing to non oriented competitive products.

There is also lots of clinical experience documented in the medical literature about the use of biodegradable polymers in intra-articular fixations. The reported problems in this field were mostly related to the use of first generation, colored PGA in 80's. We could not find any negative reports about the use PLGA in intra-articular fracture or osteotomy fixation, although fixation pins and screws made of PLGA have been on the market for more than 10 years.

Because PLGA copolymers are clinically shown to be biocompatible and Bioretec's manufacturing techniques yield high strength to the material enabling reduced mass of the implants, we expect to have a very low incidence of clinically noticeable foreign body reactions, when used even in intra-articular fracture and osteotomy fixation.