

# White Paper 6 – PLDLLA BoneWelding® Implants do not create a higher infection risk than titanium

Infections can be divided into early, delayed, and late infections. An early infection typically occurs up to three months after the surgery due to contamination during implantation. The delayed infection manifests itself between 3 to 24 months post-surgery by less virulent organisms introduced during surgery, thus leading to longer manifestation times. Late infections can be transmitted by the bloodstream and originate from an infection in another location [1].

In this white paper, the differences among metallic and biodegradable polymer implants are discussed regarding risk of infection, and possible influence of an ongoing infection on polymer degradation behavior.

## Relevance of Material

The Cochrane Collaboration published a systematic review of 30 clinical studies comparing bioresorbable and non-resorbable implants regarding infection, complications, reoperation rate, and functional outcomes. No significant differences between the two implant material groups were reported for any of the criteria, except for the lower rate of reoperations for some groups treated with resorbable implants [2], leading to an in tendency overall better outcome for resorbable implants. Only a few clinical studies were found that directly link material influence to the infection rate [3]. A clinical study covering 60 patients with 177 osteotomies showed similar infection rates for titanium and resorbable implant groups (1.53% and 1.82%, respectively), mainly due to wound dehiscences and screw loosening [4]. In a retrospective study of a Hallux Valgus fixation, it was reported that none of the 173 patients treated with the resorbable pins applied with BoneWelding® Technology required re-operation [5]. No infection was observed in a sheep study with inserted pins. A blood serum analysis with a follow-up of 36 months showed no infection at any time [6].

Since an implant always remains a foreign body, the risk of delayed and late infection is present as long said implant remains in the host. As the biodegradable implant is resorbed over time, the risk for latent infection is minimized compared to metal implants because there is no longer an implant for bacteria to attach to.

Suppose despite the potential advantages of a bioresorbable implant, an infection occurs. In that case, there is one important point to consider, namely whether there is an influence on the degradation behavior of the implant. An *in vivo* study in a rabbit model investigated the effect of an ongoing infection on two different biodegradable polymers (PLLA and PLDLLA). The authors found that the bacterial infection did not influence either mechanical properties or molecular weight of the polymers [7].

## Relevance of Implant Design and Implantation Method

A study investigating the influence of the implant design on the infection rate concludes that even though implant design and topography can play a role in the susceptibility to infection, protecting the viability of the surrounding tissue is probably even more critical. Furthermore, using a surgical technique that creates minimal damage to the intact tissue should minimize device-related infection [8].

The implantation with BoneWelding® Technology is a delicate process that does not damage the surrounding tissue [9]. The design of the Weldix® Anchor should further minimize the risk of infection due to the possibility of inserting it flush with the cortical bone. No capsule formation is observed directly above the implant during the healing process; hence the risk of infection is decreased, as there is no sealed part that the immune system cannot access. Furthermore, the BoneWelding® process does not create any dead spaces that would otherwise create a design-related infection risk [10].

In summary, neither risk of contamination per se nor the occurrence rate of infection appears to depend on the implant material. However, considering the local temperature rise and sonication at the implant surface during the BoneWelding® Process, one might speculate that this makes it difficult for bacteria to attach to the implant. The clinical literature published on ultrasonically inserted polymer implants supports this assumption, but obviously, confirmation by future studies is needed.

The use of PLDLLA as biodegradable material **obliterates the need for reoperation** for implant removal. This presents the most relevant advantage over a metallic implant, and with it, the risk of latent infection or an acute infection due to reoperation. For the Weldix® Anchor, where a small pin of PLDLLA is **inserted flush with the cortical bone**, there is a **decreased infection risk** as no fibrous capsule is formed over the implant. Furthermore, the BoneWelding® process is a delicate **implantation process with a shallow risk of damaging the surrounding viable tissue**, which minimizes the risk of device-related infection.

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