

PRESS RELEASE

Bio-Gate: Update on the HIPrevision clinical trial for HyProtect™-coated hip revision implants

- **Study protocol published in the internationally recognized peer-reviewed journal Trials (Springer Nature/BMC)**
- **Multicenter, randomized controlled trial at 10 centers in Germany, Poland, and Spain involving over 200 patients**
- **Further step in the clinical development of HyProtect™-coated revision implants**

Nuremberg, 23 June 2026 – Bio-Gate AG (ISIN DE000BGAG981), a leading provider of innovative healthcare technologies, provides an update on the current status of the clinical development of the HyProtect™ coating for orthopedic implants: Following the completion of the pilot phase, the comprehensive main clinical trial has now commenced. The project – conducted in collaboration with a project partner and initially announced in December 2024 – is on track to reach the next milestone toward CE approval of HyProtect™-coated revision implants.

Successful completion of the pilot phase

The pilot phase (Part A) of the study, which began in June 2025, was initiated as safety assessment of the HyProtect™-coated investigational devices in a small number of patients. In Part B, over 200 additional patients will now be enrolled across a total of 10 study centers in Germany, Poland, and Spain.

Study protocol published in a renowned journal

In February 2026, the complete study protocol was published in the internationally recognized, peer-reviewed journal Trials (Springer Nature/BMC) (Alt et al., Trials 2026;27:174: <https://pmc.ncbi.nlm.nih.gov/articles/PMC12930628/>). Publication in a peer-reviewed journal underscores the scientific quality of the study design and ensures full transparency for the medical community and the methodology of the clinical trial. The study is also registered on ClinicalTrials.gov (NCT06737809) and in the European database Eudamed (CIV-24-05-047447).

Study design with high standards of scientific validity

To the authors' knowledge, HIPrevision is the first randomized controlled superiority trial worldwide to investigate the clinical efficacy of a silver-coated versus an uncoated hip revision implant system in the treatment of periprosthetic joint infections (PJI). The primary endpoint is the infection rate 12 months after revision surgery. Further data can be found in the publication in *Trials* (Springer Nature/BMC; Alt et al., *Trials* 2026;27:174). The assumptions underlying the study are based on previous data and additional scientific findings.

Previous clinical experience complements the interpretation of the ongoing study

The assumption underlying the HIPrevision study – namely, a reduction in the reinfection rate – is based, among other things, on existing clinical experience with the HyProtect™ technology. Over the past decade, more than 170 high-risk patients worldwide have been treated with HyProtect™-coated orthopedic and trauma implants – as part of customized special-order devices, therapeutic trials, and compassionate use programs in Europe, North America, and the Asia-Pacific region. The patients treated were predominantly those with multiple prior surgeries due to infection, severe comorbidities, or tumor diseases – patient groups in which reinfection rates are significantly elevated according to scientific studies and which can exceed a 50 percent reinfection in cases of repeated septic revisions.

The (re)infection rate documented in this high-risk population following HyProtect™ application was reported to be between 2.6 and 6.4 percent. Sixteen of the treatments were scientifically analyzed in eight peer-reviewed journal articles.

This real-world data – together with preclinical animal and in vitro studies – are taken into account in the HIPrevision study when deriving the underlying assumption of a reduction in periprosthetic re-infections.

High clinical need

Periprosthetic joint infections are among the most serious complications of endoprosthetics. In Germany alone, according to the German Endoprosthesis Register (EPRD), 199,052 primary hip joint implantations and over 38,000 revision surgeries were documented in 2024 – and the trend is rising. In hip revisions involving total replacement, the risk of a recurrent periprosthetic infection is particularly high: within 12 months, 16.4 percent of affected patients must undergo surgery again due to a reinfection. Including non-revised reinfections, the actual rate is approximately 21.5 percent.

Periprosthetic infections also place a significant economic burden on the healthcare system. While the direct hospital costs of a primary hip replacement in Germany range from approximately 8,000 to 16,000 euros, the direct treatment costs for a two-stage replacement due to a periprosthetic infection rise to around 40,000 euros per patient (Szymiski et al., *Journal of Arthroplasty* 2024). If an infection with multidrug-resistant organisms (MDR) also occurs, this results in an average of approximately 27,000 euros in additional costs per case (Willy & Bröcker, *Bundesgesundheitsblatt*

2025) – the treatment of a single MDR-PJI case can thus reach total costs of 70,000 to 120,000 euros.

Periprosthetic infections: “A life-threatening complication with mortality rates on par with cancer” (Prof. Nicholas M. Bernthal; Master Class: Current Concepts in the Management of Implant Infection and Bacterial Contamination in Complex Orthopedic Procedures; Oct. 30, 2024)

The importance of effective infection prevention is particularly evident in long-term mortality rates. A Canadian registry analysis of 175,432 patients shows that patients with a periprosthetic infection following hip replacement have a 10-year mortality rate of 11.4 percent – compared to just 2.2 percent among patients without infection. This corresponds to a more than fivefold increase in the risk of death (Mundi et al., Journal of Bone and Joint Surgery 2024).

Prof. Nicholas M. Bernthal, Chair of Orthopedics at the David Geffen School of Medicine at UCLA and one of the world’s leading experts on periprosthetic infections, summarizes this as follows: “Mortality following a periprosthetic infection falls within a range comparable to the mortality rates of common cancers – between breast and colorectal cancer.” Periprosthetic infections are associated with a significant clinical burden for affected patients. A recent meta-analysis of nearly 20,000 patients shows that hip PJI is also associated with a significant risk in terms of mortality (Ramos et al., Journal of Arthroplasty 2025).

Periprosthetic infections are thus not merely a serious orthopedic complication, but a life-threatening condition with mortality rates on par with cancer. The need for effective infection prevention, as pursued with HyProtect™ technology, is therefore all the more critical.

Significant economic burden

In the Bundesgesundheitsblatt, Willy & Bröcker 2025 estimate that, on a national level in Germany, infections with multidrug-resistant pathogens cause additional costs of approximately 4 billion euros annually. This underscores the health policy relevance of the topic of infection prevention.



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About Bio-Gate AG – The medical technology company Bio-Gate AG develops and markets applications which use unique silver technology to help prevent infections and thus to improve health. Bio-Gate AG's specialty is using pure silver to treat materials and surfaces that are used in all areas of daily life – thus providing long-term and medically effective protection against bacteria, microorganisms and other pathogens. Bio-Gate AG works in three fields to supply a variety of products that provide antimicrobial protection: material enhancement, surface coating and testing the antimicrobial or anti-adhesive properties of materials. The Nuremberg-based company offers systems that stretch across the entire value-adding chain, from development to approval to production. For more information, please visit www.bio-gate.de.

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