PRESS RELEASE

Bio-Gate AG: First Comparative Clinical Data on HyProtect™ in Trauma Care— Significantly Higher Treatment Success Rate for Infected, Non-Healed Femur Fractures

- **Direct clinical comparison of HyProtect™-coated versus uncoated osteosynthesis implants**
- **Treatment success at 12 months: 100 percent success in the group coated with Bio-Gate's HyProtect™ technology versus 61 percent in the control group**
- **Significantly lower inpatient treatment costs, by around 31 percent. Published in the peer-reviewed journal Injury (Elsevier)**

Nuremberg, 15 September 2026 – Bio-Gate AG (ISIN DE000BGAG981), a leading provider of innovative healthcare technologies, announces the publication of a clinical study on HyProtect™ technology in the internationally recognized peer-reviewed journal Injury (Elsevier). HyProtect™ is an ultrathin plasma coating of pure silver and polysiloxane developed by Bio-Gate to protect surfaces against bacterial growth. The newly published cohort study (REFECT) compares HyProtect™-coated implants with uncoated implants in the treatment of infected femoral shaft pseudarthrosis (non-union of femoral fractures). The treatment success rate after twelve months was 100 percent in the coated group, compared to 61 percent in the uncoated control group.

Direct Comparison: Coated vs. Uncoated

Previous clinical evidence regarding the ultrathin silver-polysiloxane coating HyProtect™ was based on case reports, more than 175 individual named-patient treatments, and more than 215,000 implants used in animals. The study now published (*Mueller MM, Niclassen CM, Kowald B, Klinger CE, Gerlach UJ, Grimme C, Schulz AP, Frosch KH, Schoop-Schmetgens R. Higher Rate of Treatment Success of Infected Femoral Shaft Non-unions with Ultrathin Silver-Polysiloxane-Coated Implants. Injury 2026;57:113586. doi: 10.1016/j.injury.2026.113586*) is a direct comparison of HyProtect™-coated implants and an uncoated control group. It also represents the largest reported patient cohort to date with infected femoral shaft pseudarthrosis (non-union of femoral fractures)—a rare and clinically challenging condition.

Implications for the Clinical Development of HyProtect™ Technology

This publication supplements the existing evidence base for HyProtect™ technology with additional comparative clinical data. It complements the applications documented worldwide over the past decade in more than 175 high-risk patients, as well as the ongoing multicenter, randomized controlled pivotal trial HIPrevision on HyProtect™-coated hip revision implants (Alt et al., Trials 2026;27:174; NCT06737809), whose transition to the main phase was announced by Bio-Gate in June 2026.

Marc Lloret-Grau, CEO of Bio-Gate AG, comments on the findings: “In this study, the coating was effective in trauma care as well and was associated with lower treatment costs. Until now, its effectiveness in practice had been demonstrated and documented only in individual cases. This study shows that success for the first time in a larger cohort. The time dimension is striking as well: no patient with a HyProtect™-coated implant suffered a recurrent infection within twelve months, and in every case the bone healed (no recurrent pseudarthrosis). The authors designed and analyzed the study without our involvement and conducted it without our funding – which gives the data particular weight as evidence for our HyProtect™ technology. For the first time, a direct clinical comparison between HyProtect™-coated and uncoated trauma implants is available, in patients for whom conventional treatment frequently reaches its limits. Our clinical focus has so far been on joint replacement – the replacement of a joint with an artificial prosthesis, in hips and knees. Trauma care is the second large field of application for HyProtect™: worldwide, implants worth USD 9.6 billion were sold in this segment in 2025, around

15 percent of the global orthopedic market. We are already working with an internationally active implant manufacturer in this segment."

Study Design

One of the most challenging cases in trauma surgery is when a thigh bone fractures and the fracture fails to heal after surgery - all the while an infection also simultaneously takes hold of the bone.
Affected patients have often already undergone multiple surgeries, spent months in treatment, and, in the worst-case scenario, may require leg amputation. It was precisely these patients who were treated in the study.

REFECT is an investigator-initiated trial: initiated, sponsored and analyzed by the treating hospital. Bio-Gate was neither the sponsor nor the commissioning party of the study. The prospective cohort study included 70 patients who were treated between 2013 and 2024 for infected femoral shaft pseudarthrosis (non-union of femoral fractures). Eight patients received HyProtect™-coated plates starting in 2023. Sixty-two previously treated patients who had received conventional, uncoated implants formed the historical control group. The primary endpoint was treatment success at 12 months, defined as bone union, full weight-bearing capacity, and freedom from reinfection. The study is registered in the German Registry of Clinical Trials (DRKS00034424) and was approved by the competent ethics committee (vote 2023-101020-BO-ff).

Results

- No patient with a HyProtect™-coated implant suffered a recurrent infection or recurrent pseudarthrosis within twelve months (in no case did bone healing fail).
- The treatment success rate was 100 percent compared to 61.3 percent in the control group.
- In the control group, 20.9 percent of patients had a recurrent infection at twelve months and 12.9 percent showed failure of bony consolidation (bone healing). Over the entire observation period these figures rose to 24.2 and 22.5 percent respectively. Five treatments were ultimately classified as failed.
- The baseline situation in the HyProtect™ coated group was less favorable: All patients had complex fractures (100 percent compared to 54.8 percent in the control group), and multidrug-resistant or difficult-to-treat pathogens were detected in 75 percent of them.
- Patient-reported quality of life (EQ-VAS) improved significantly in the coated group compared to the preoperative baseline.

	HyProtect™-coated	**Uncoated**
Results at 12 months (primary endpoint)		
Treatment success	✓ **100%**	61.3%
Reinfection	✓ **0%**	20.9%
Failure of bone healing	✓ **0%**	12.9%
Baseline condition prior to treatment (higher values = more challenging baseline condition)		
Complex fractures (AO Type C)	100%	54.8%
Multidrug-resistant / difficult-to-treat pathogens	75%	30.6%
Open fractures	50%	43.5%
Multiple trauma	62.5%	46.8%
Overall treatment course		
Failed treatments	✓ **0**	5
Inpatient treatment costs (DRG)	✓ **€33,886**	€48,937

Context: Why the Severity of Fractures Matters

Fracture-related infections (FRI) are not evenly distributed across all bone fractures. The risk of FRI increases with the severity of the injury and the amount of energy involved: Following simple, closed fractures, the infection rate is in the low single-digit percentage range, whereas following high-energy open fractures of long bones, it reaches up to 42 percent. It is precisely this high-risk profile that characterizes the coated group in the published study: All patients had the most complex type of fracture, half had open fractures, and just under two-thirds had multiple traumata.

An international group of experts led by Metsemakers describes fracture-associated infections in The Lancet Infectious Diseases as a complication with significant clinical and socioeconomic consequences, the global extent of which has not yet been adequately documented. The group calls for giving this condition higher priority in research and clinical care, standardizing treatment protocols, and providing appropriate compensation for the substantial personnel and infrastructure resources required (*Metsemakers WJ, Moriarty TF, Morgenstern M, et al. The global burden of fracture-related infection: can we do better? Lancet Infect Dis. 2024;24(6):e386–e393. doi: 10.1016/S1473-3099(23)00503-0*). Against this backdrop, the lower complication rate observed in the study and the inpatient treatment costs that are approximately 31 percent lower are also of interest from a health economics perspective.

Economic Outcomes

The cumulative DRG costs for inpatient care in the coated group, at 33,886 euros, were significantly lower than those in the control group, at 48,937 euros—a difference of approximately 31 percent. The publication attributes this to the markedly lower complication rate. Length of stay and the number of surgeries were also lower in the coated group, without reaching statistical significance.

Tolerability

A single HyProtect™ implant contains about half a milligram of silver. The publication puts this at about a thousand times less than in conventional silver-coated megaprostheses for cancer patients. Only very small amounts of silver were detected in the patients' blood, and at the last follow-up examination, all levels had returned to the normal range. The grayish discoloration of the skin (argyria) associated with high silver levels did not occur in any patient.

Note on the study

This release reports the results of a scientific publication produced independently of Bio-Gate. REFECT is an investigator-initiated trial. The sponsor is the treating hospital, not Bio-Gate. Neither the hospital nor the authors of the study were involved in this release or authorized it. Bio-Gate coated the implants used in the study and supplied the characteristics of the coating. The company was not involved in the design, conduct or analysis of the study.

Contacts

Bio-Gate AG
Neumeyerstr. 28-34
90411 Nuremberg
Germany
www.bio-gate.de

North America
Karl Richter
RFH BioTek Inc.

Tel: 416-407-6120
rfh@rfhBioTek.com
Toronto, Canada

Europe
Falk von Kriegsheim
rikutis consulting
fvk@rikutis.de
presse@bio-gate.de
Tel. +49 (0) 911 477523-222
Mobil +49 (0)172 9837109

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.

Disclaimer