

# Medical solutions



PLATIT® *11* - Series

PLATIT®

# Antibacterial coatings for the medical industry

## Bacteria and their consequences

Bacteria were among the first species on earth and are present in most of its habitats. They live in soil, water, acidic hot springs, radioactive waste, and deep in the Earth's crust. A gram of soil contains around 40 million bacterial cells, and a milliliter of fresh water has about a million. Bacteria vary in shape and can be classified into two major groups based on Gram-staining: gram-negative and gram-positive.

Many bacteria are pathogenic and cause diseases like cholera, syphilis, bubonic plague, anthrax, and leprosy. The most common fatal bacterial diseases are

respiratory ones, with tuberculosis killing about two million people annually, mostly in Sub-Saharan Africa. Antibiotics treat bacterial infections but contribute to antibiotic resistance, a growing problem.

In the USA, about 100,000 deaths occur annually from Healthcare-associated infections (HAI). In a three-year study, surfaces of frequently touched objects in a healthcare facility were replaced with copper and its alloys. This led to a significant reduction in bacterial burden, ranging from 50% to 98%.

## PLATIT's certified solution

Despite successes, practical implementation of these approaches faces economic and technical challenges. Antibacterial PVD coatings offer a solution by providing bactericidal surfaces that reduce hand-transmitted diseases without altering the bulk properties of components. PLATIT's antibacterial coating, compliant with ISO 22196:2011-08, has shown excellent bactericidal properties and durability in tests simulating real-world conditions. Additionally, it boasts high hardness, elastic modulus, and good adhesion to substrates (Table 1).

### ISO certified tests (performed at Hohenstein Laboratories – Germany):

The PLATIT's developed antibacterial coating tested under ISO 22196:2011-08 standard exhibits a profound bactericidal performance for both gram-negative, i.e., Escherichia Coli and gram-positive, i.e., Staphylococcus Aureus. According to DIN EN ISO 20743:2013, highest efficacy level of antibacterial properties is achieved when reduction value A [lg cfu] is higher or equal to 3.

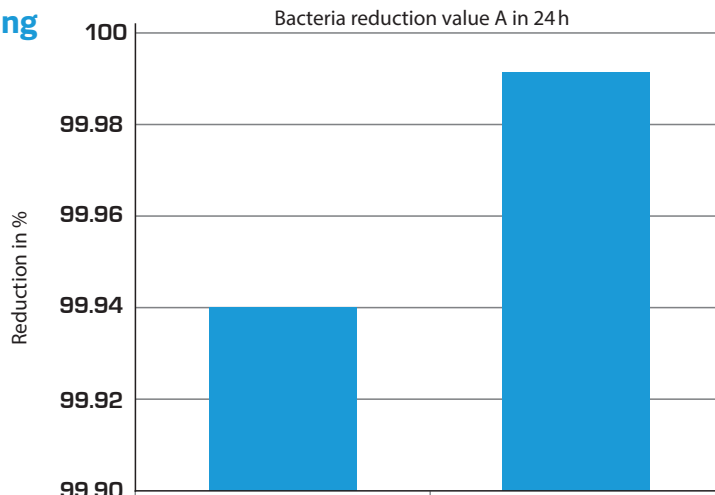
**Table 1. Mechanical properties of PLATIT's antibacterial coating:**

#### Specifications

Color	Gold
Deposition technology	Cathodic arc
Nano-hardness [GPa]	25–27
Elastic modulus [GPa]	460
Coating thickness [µm]	1–2
Adhesion [Rockwell]	HF1
Coating temperature [°C]	200–450



## TiAgN coating



	Staphylococcus Aureus ATCC 6538P	Escherichia Coli ATCC 8739
Reduction %	≥99.94 %	99.992 %
Ig cfu	≥3.2	4.15

Staphylococcus Aureus concentration of inoculum\*:  $4.77 \times 10^5$  cfu/ml\*\*

Escherichia Coli concentration of inoculum:  $6.45 \times 10^5$  cfu/ml

The value of gram growth is calculated over 24 h on the sample in comparison to the reference material and according to the formula:

$$S = [\lg(B/A) - \lg(C/A)] = [\lg(B/C)]$$

S: specific antimicrobial activity

A: average number of active bacteria (cfu), eluted from the reference material immediately after inoculation

B & C: average number of active bacteria (cfu), eluted from the reference material and sample (respectively) after 24 h incubation

\* An inoculum is the population of bacteria that is introduced in the fermentation medium or any other suitable medium

\*\* Colony forming unit per milliliter

## Certified long-term behavior

For medical implants, bactericidal properties are crucial during the first two post-surgical weeks. However, for other coated components, these properties should last for weeks or months despite multiple uses, cleanings, and touches. To simulate real usage conditions for the developed antibacterial coating, two approaches were used:

### 1. 50 autoclave cycles (performed at RMS Foundation, Switzerland):

Antibacterial coated parts underwent 50 autoclave cycles to mimic the conditions of medical instruments. These parts were then tested at Hohenstein Laboratories under ISO 22196:2011-08 to ensure sustained bactericidal efficacy.

Each autoclave cycle: 1x vacuum (20 kPa) / steam burst (160 kPa),

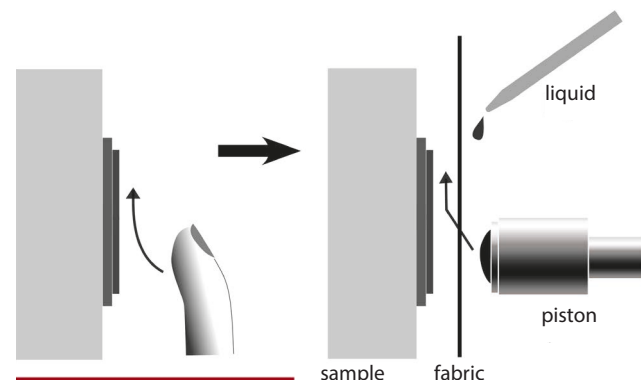
Sterilization (15 min at  $120 \pm 2^\circ\text{C}$ ), drying (5 min)

### 2. 50,000 touches (tribo-touch testing with 50,000 strokes at KIMW Lüdenscheid – Germany):

To simulate frequently touched public objects (e.g., door handles, elevator buttons), the antibacterial coating underwent 50,000 strokes in a tribo-touch

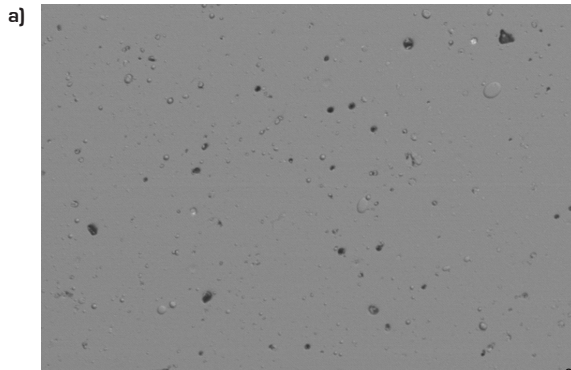
test. The coating was then tested for bactericidal properties under ISO 22196:2011-08. The coating demonstrated high hardness ( $\geq 25$  GPa) and minimal surface change, indicating it can endure extensive use with almost no mechanical deterioration.

**Figure 1. Schematic depiction of the test by Co. Tribotron resembling a frequently touched surface:**

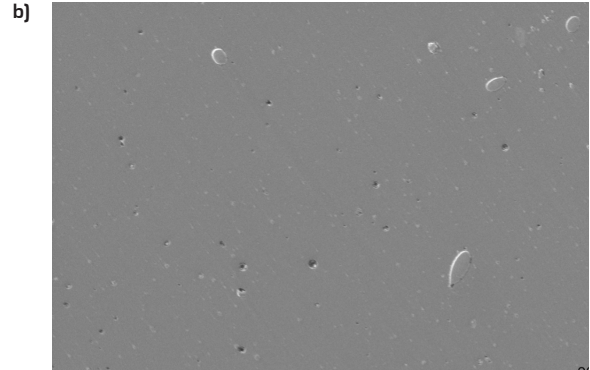


Testing distance: 5 mm, No. of cycles: 50,000 strokes, testing frequency 2 Hz, test media: artificial hand perspiration acc. to 8.13 of the standard, media feed: 0,5 ml / 400 cycles, testing force: 6 N, test plunger:  $\varnothing 10$  mm.

**Figure 2. Scanning electron microscopy (SEM) images of the antibacterial coatings before (a) and**

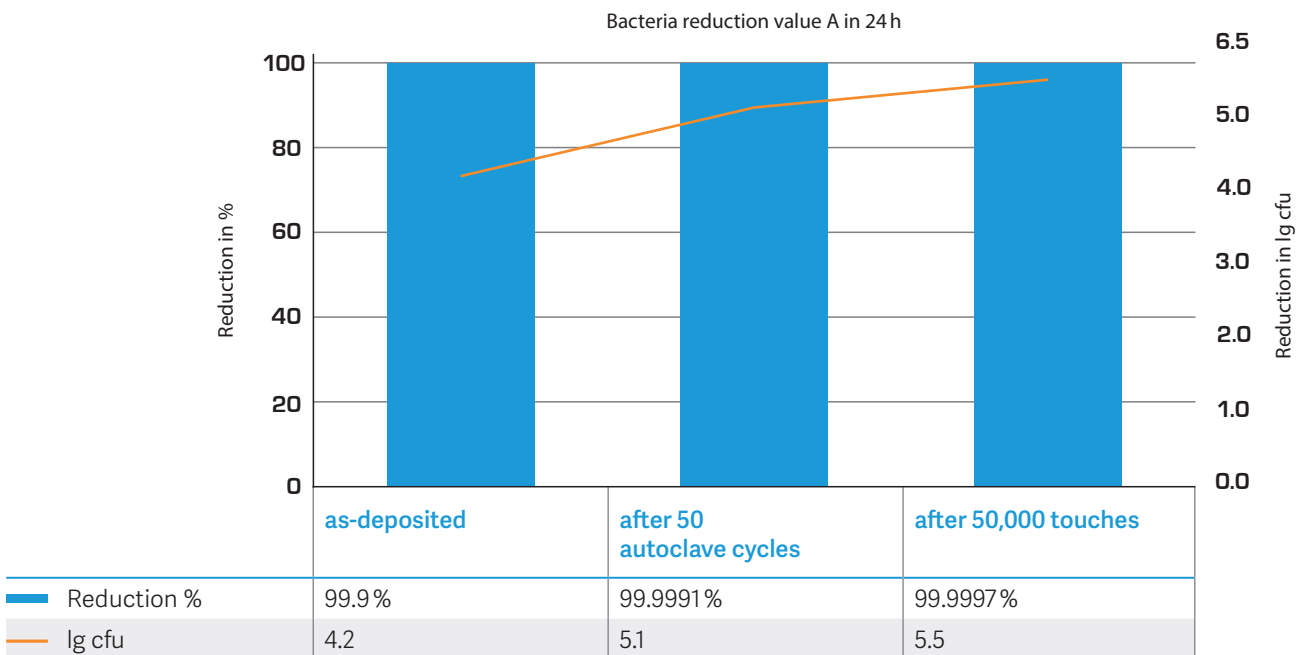


**after (b) 50,000 strokes, i.e. touches, in the tribo-touch test:**



Results from antibacterial tests under ISO 22196:2011-08 standard for Escherichia Coli demonstrates the highest level of bactericidal performance even after 50 autoclave cycles or 50,000 touches (figure 3). These results significantly expand the applicability of the developed antibacterial coatings into a broad range of components and applications. Numerous examples from healthcare system and healthcare acquired infections (HAI) thereof to frequently touched surfaces in public space can be considered.

**Figure 3. antibacterial performance against Escherichia Coli according to ISO 22196:2011-08 standard; status before (as-deposited) compared to after 50 autoclave cycles and 50'000 touches. In all cases, the highest level of bactericidal performance defined by ISO standard have been achieved:**



Ref.

[1] M. Heron et al. "Deaths: Leading Causes for 2009", National Vital Statistics Reports 2012, vol.61, No.7, Agency for Healthcare Research and Quality, Patient safety primers: healthcare-associated infections 2012.

[2] M. G. Schmidt et al. "Sustained Reduction of Microbial Burden on Common Hospital Surfaces through Introduction of Copper", Journal of Clinical Microbiology vol. 50, No. 7, 2012, P. 2217.

## Advanced coating solutions for medical applications

At PLATIT, we provide both small coating units for specific processes and large machines for cost-effective production. Our offerings include individualized coating processes, intelligent holders for various medical instruments, and complete turnkey systems covering all upstream and downstream steps of hard coating.

Our DLC coatings offer a perfect black finish, either arced or sputtered, tailored to your requirements. The Pi111 family, including the Pi111 PLUS G3 and Pi111 TRM, supports both methods.



### PLATIT Pi111 PLUS G3

The Pi111 PLUS G3 is the third generation of PLATIT's small PVD coating unit. It offers short cycle times, simple operation and high user-friendliness at an attractive price – without compromising on coating performance. Thanks to two rotating cathodes with arc technology, the unit enables to deposit selected PLATIT Signature Coatings in reproducible high-quality.

The Pi111 PLUS G3 is the best choice for customers looking for a high-quality entry into the coating world or those who want to add a fast, low-volume PVD unit to their machinery.

- Fast high-quality coatings with excellent adhesion
- In the tooling industry, arc coating units are preferred unless the disadvantages of arcing – such as droplets – need to be eliminated



### PLATIT Pi111 TRM

The Pi111 TRM is a state-of-the-art PVD coating unit featuring PLATIT's Twin Rotary Magnetron technology. Its two rotating sputter cathodes with advanced magnetron technology deliver dense, droplet-free coatings essential e.g., for micro tools and challenging applications such as reamers or taps. The Pi111 TRM ensures superior coating performance and flexibility. Ideal for manufacturers seeking a fast, efficient sputtering machine with the latest technology at a reasonable cost, the Pi111 TRM is the perfect addition to any advanced coating operation.

- Dense coatings thanks to the pulsing which is very important for challenging applications such as micro tools due to the small geometry of the application
- Smooth surface free of droplets
- Both metals as well as low thermal conductivity materials such as pure ceramics can be used as targets
- Highly energetic ions with high impart have enough energy to go in substrate voids

## Medical applications of PLATIT coatings

While coating tools is mostly intended to extend service life, medical instruments are usually coated to give them certain positive properties for use in operations. Whether it's different colors to make it easier to tell instruments apart for different purposes, or coatings that protect them from the harsh chemicals of sterilization.

PLATIT coatings have been used in medical technology for many years. Our PVD coating units provide desired characteristics to instruments used in operating rooms and practices.

Our coatings offer:

- Matting to reduce light reflection during operations
- Protection from cleaning fluids and sterilization cycles
- Enhanced scratch resistance
- Sharp cutting-edges for quicker wound healing
- Reduced friction
- Protection for patients from damage or impairment
- Lower risk of infection and possible revision procedures
- Antibacterial properties for complex applications difficult to sterilize
- Various colors to differentiate between applications

Our TiN, DLC, ZrN, TiCN, CrN and AlTiN coatings meet all requirements of international health organizations. Meanwhile, they are also tested for biocompatibility and certified accordingly by NAMSA by passing the MTS cytotoxicity (ISO10993-5) and intracutaneous reactivity (ISO10993-10) tests.

NAMSA

Summary of Biocompatibility Tests

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Test Article Name	AlTiN PVD coated Ti6Al4V plates		
Article Identification	Reference: Biocompatible uncoated Ti6Al4V material, Batch: AlTiN		

Test	Standard	Study number	Results
ISO MTS cytotoxicity test	ISO 10993-5 (2009)	292764	Pass*
ISO Intracutaneous Study in Rabbits (Two Extracts)	ISO 10993-10 (2010)	292765	Pass*

\*. Conclusions apply only to the test article as received and tested.  
Only the final reports are legally acceptable.

Approved by: Date: August 05, 2021

Aizé Laffitte  
Associate Study Director



<https://www.platit.com/en/downloads/#cat-certificates>

As with all aspects of medicine, the testing and documentation standards for medical instruments are very high. This is matched by the fact that PLATIT's process control software supports precise documentation, process control, and batch-by-batch traceability of coating processes. The connection to an ERP system also allows this documentation to be passed on to healthcare databases.

With PVD coating units from PLATIT, medical coatings meet the highest standards, helping to improve patient care globally.

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