WHITEPAPER

HYDAK® Hydrophilic Coatings for Metal Substrates

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Introduction

Metal substrates are extensively utilized in medical devices to facilitate precise access to treatment areas. To enhance the functional performance of these substrates, manufacturers employ various approaches to improve device lubricity, such as polymeric claddings and specialized coatings. Biocoat, a recognized leader in hydrophilic coating innovation, has developed advanced, high-performance, PFAS-free (per- and polyfluoroalkyl substances-free) hydrophilic coatings designed specifically for application on metal substrates. This paper examines the critical need for hydrophilic coatings on metal substrates and evaluates the performance of Biocoat's HYDAK® hydrophilic coatings on commonly used metals in medical devices.

Metal Substrates in Medical Devices

Metal substrates are integral to a wide range of medical devices due to their mechanical properties and versatility. These devices often incorporate multiple metal types to fulfill specific functional requirements. For instance, guidewires may combine a nitinol core, stainless steel coil, and platinum tip to achieve optimal performance. Other medical devices leveraging metal substrates include hypotubes, nose cones, stents, coils, and similar components.

Types of metals for medical devices:

- Stainless steel
- Nitinol
- Platinum
- Gold
- Nickel
- Titanium

Common device types with metal substrates:

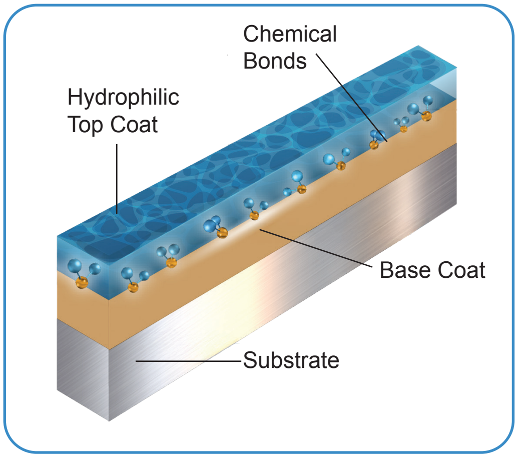
- Guidewires
- Hypotubes
- Stents
- Nose cones
- Coils
- And more

Many of these devices demand superior lubricity to enable smooth navigation through anatomical pathways while minimizing tissue trauma. Achieving the necessary lubricity represents a significant engineering challenge. A conventional solution involves the application of polymer claddings to the metal substrate, often incorporating polytetrafluoroethylene (PTFE) or other PFAS-based materials to achieve the desired friction reduction.

However, PFAS compounds are characterized by persistence and bioaccumulation, posing significant environmental and human health concerns. These substances are resistant to degradation, persist in ecosystems, and can accumulate within biological systems, including the human body. While comprehensive, long-term research remains incomplete, emerging evidence correlates PFAS exposure with adverse health effects, including certain cancers and reproductive issues.[1] This has led regulatory bodies, such as those in the European Union, to propose stringent restrictions on PFAS usage.

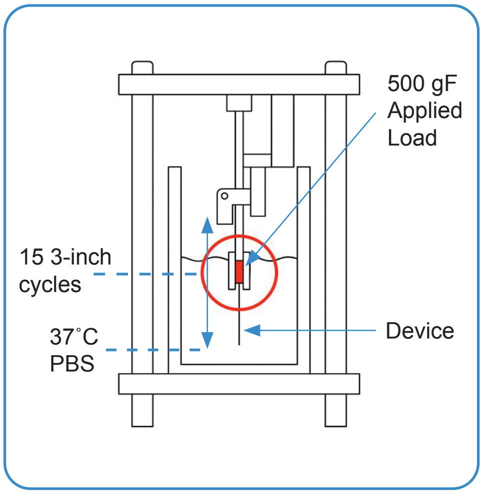
Additionally, the PFAS supply chain has faced significant disruptions. Prominent manufacturers, including 3M, have announced plans to exit the PFAS market due to mounting regulatory and legal challenges.[2] Consequently, medical device manufacturers are actively seeking alternative solutions that eliminate PFAS while maintaining or exceeding the required levels of lubricity and durability.

Biocoat's HYDAK® hydrophilic coatings provide a high-performance, PFAS-free coating solution specifically engineered for metal substrates. These bi-laminar coatings form a robust bond with the substrate, ensuring durability throughout extended medical procedures. Unlike traditional coatings, HYDAK coatings do not require primers or tie-coats, optimizing processing efficiency while reducing material requirements. The coatings are available in both UV-cured and thermally cured options, providing manufacturers with greater flexibility without compromising the superior performance required for medical applications. Biocoat's engineering team has rigorously evaluated HYDAK coatings to validate their performance on metal substrates commonly utilized in medical device manufacturing.



HYDAK UV and Thermal Coating Testing Methodology

To assess the performance of HYDAK UV and thermal coatings, rigorous testing was conducted on coated devices and materials. Testing methodologies were tailored to account for the properties and configurations of the metal substrates.

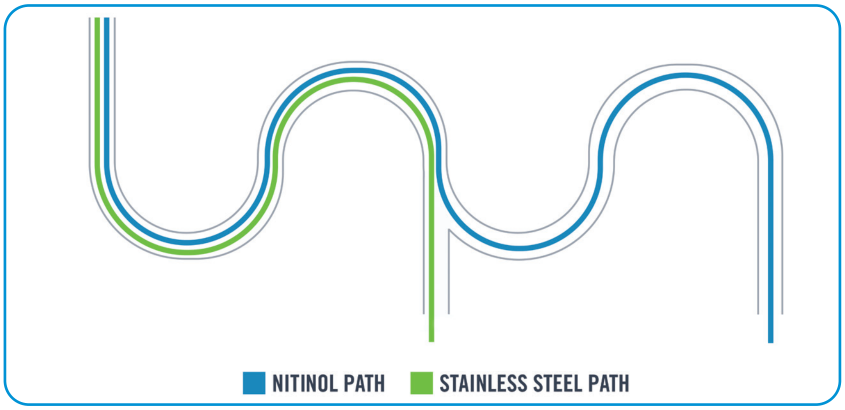


For 0.030" diameter wires, durability and friction were evaluated using a 30-cycle pad friction test. Devices were coated with HYDAK UV and thermal coatings and subjected to a controlled testing environment featuring a 37°C phosphate-buffered saline (PBS) bath. During testing, coated wires were pulled through closed pads at a force of 500 gF for 30 cycles. Frictional forces were measured during cycles 2-4 and cycles 28-30 to assess the wear resistance and durability of the coatings over repeated use.

For 0.014" diameter wires, which exhibit increased flexibility, a tortuous track test model was employed instead of the pinch test (Figure 1). Wires fabricated from stainless steel or featuring platinum or PTFE coatings were tested using a single "S" track with a 1 cm radius of curvature. In contrast, nitinol-based wires were tested using a double "S" track configuration due to their inherent flexibility.

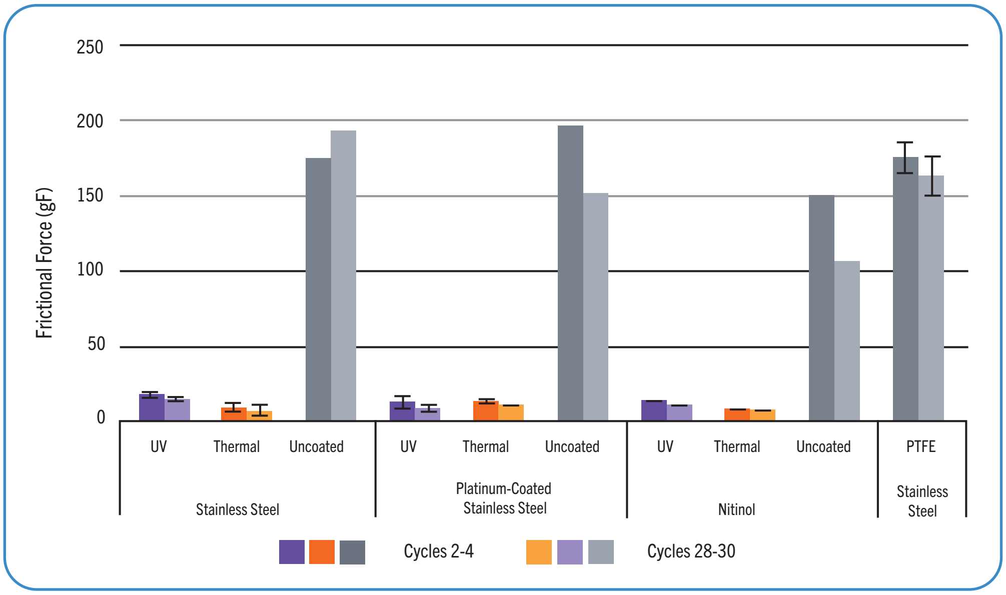
During testing, devices were passed through tortuous track configurations 15 times using PBS as a hydration agent within Tygon® PVC tubing. Frictional forces were recorded, following the same methodology applied to 0.030" devices, to evaluate coating performance under dynamic conditions.

Figure 1: Tortuous Path Test Diagram



HYDAK® UV and Thermal Coating Testing Results

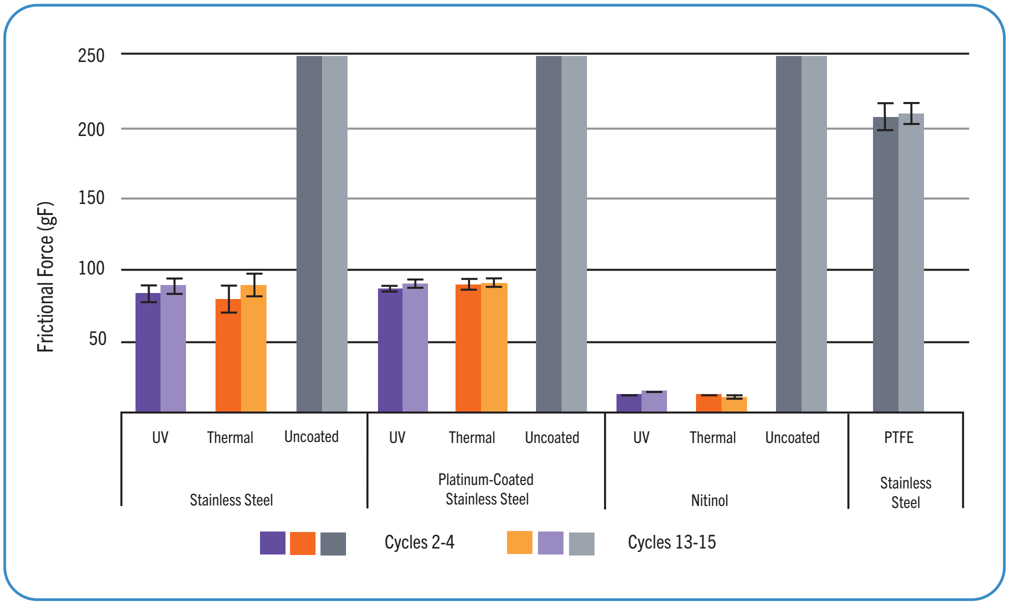
Figure 2: Frictional Force on 0.030" Mandrels Using Pinch Test



A cycle accounts for one 3" pull through the friction pads. Cycles 2-4 are represented by the darker shades and cycles 28-30 are represented by the lighter.

The HYDAK UV and thermal coatings significantly enhance the lubricity of stainless steel, platinum-plated stainless steel, and nitinol substrates. Frictional force testing demonstrated that both coatings reduced friction by more than 90%. For instance, uncoated stainless steel exhibited initial frictional forces of 175 gF, whereas HYDAK thermal and UV coatings reduced these values to 8 gF and 14 gF, respectively. By comparison, PTFE-coated stainless steel presented a higher initial frictional force of 127 gF.

Figure 3: Frictional Force on 0.014" Wires Using Tortuous Path Test



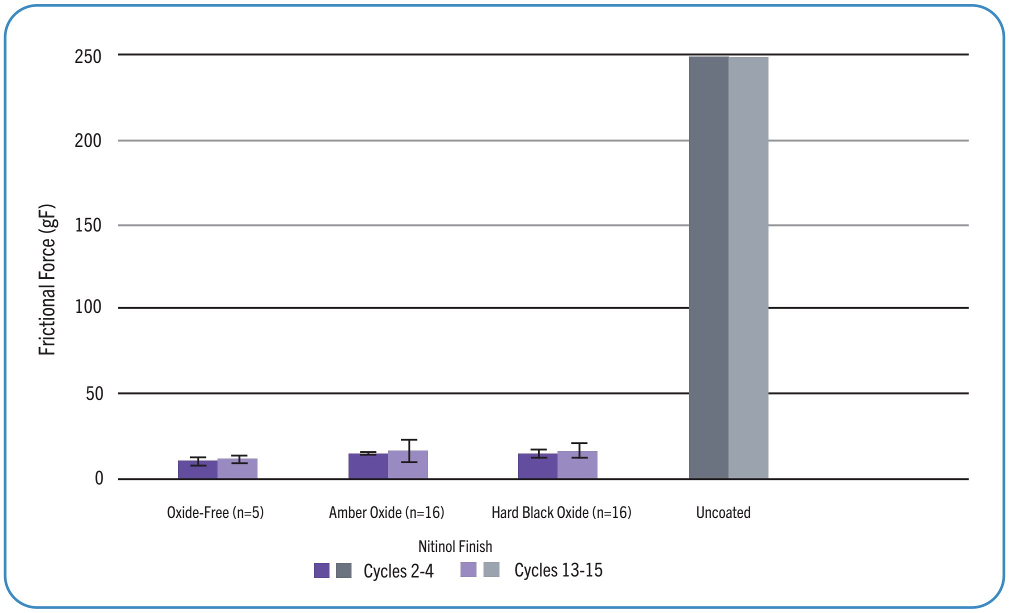
Uncoated 0.014" stainless steel, platinum-plated stainless steel, and nitinol wires were unable to complete the track test model due to exceeding the load cell threshold (>250 gF) during the first cycle.

PTFE-coated stainless steel wires maintained high frictional forces, approximately 210 gF, over 15 cycles. Conversely, HYDAK UV and thermal coatings exhibited significantly lower frictional forces of 80-90 gF, with a minimal variance of less than 10 gF over 15 cycles, demonstrating excellent durability and consistent performance throughout the testing process.

Performance of HYDAK® UV Coatings on Nitinol Substrates

Nitinol, a nickel-titanium alloy, is widely utilized in medical device applications due to its superelasticity and shape memory characteristics. Different surface finishes on nitinol, such as oxide-free, amber oxide, and black oxide, are employed to achieve specific surface properties. For hydrophilic coatings to be effective in such applications, they must adhere robustly to these various surface finishes. To assess the adhesion and performance of HYDAK UV coatings on nitinol, Biocoat conducted tests on 0.014" nitinol wires with varying surface finishes, including oxide-free, amber oxide, and black oxide.

Figure 4: Frictional Force on 0.014" Wires Using Double "S" Track Test



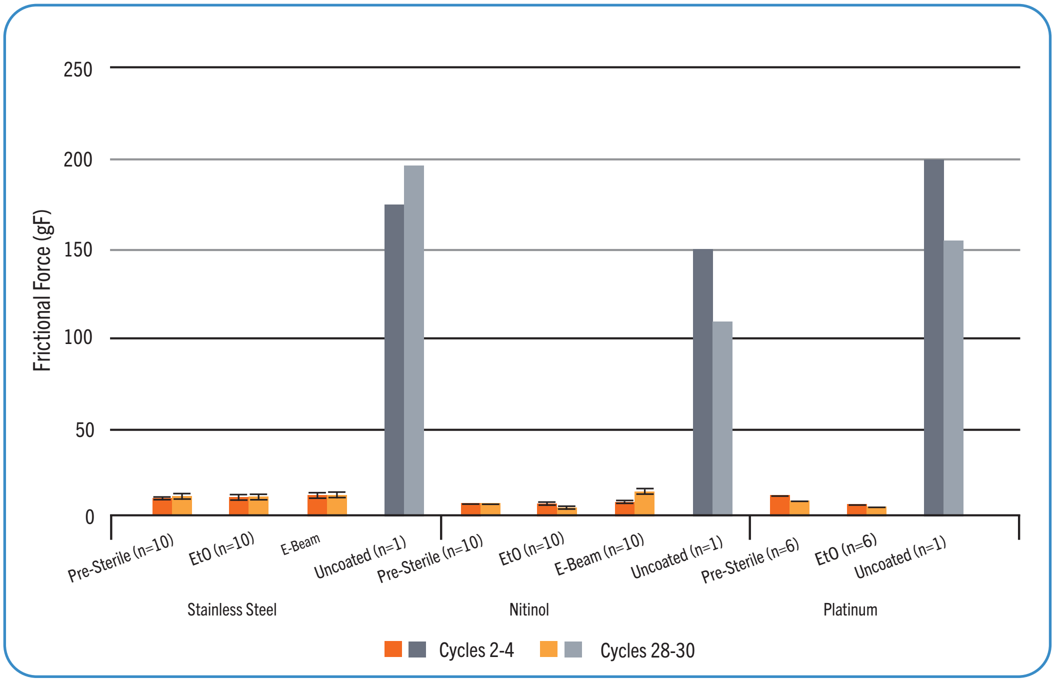
Results indicated that HYDAK UV coatings provided exceptional lubricity across all finishes. In frictional force testing, uncoated nitinol wires maxed out the load cell (>250 gF) within the double “S” track test configuration, while HYDAK UV-coated wires demonstrated frictional forces below 20 gF, marking a greater than 90% reduction in frictional force. These findings underscore the versatility and efficacy of HYDAK UV coatings across diverse nitinol surface finishes.

Sterilization Compatibility of HYDAK Coatings

Sterilization is a critical process in the manufacturing of medical devices, ensuring sterility and patient safety. Common methods include ethylene oxide gas (EtO) sterilization, which is widely employed for interventional vascular devices, and E-beam sterilization, a rapidly emerging alternative known for its efficiency, cleanliness, and environmental benefits. Hydrophilic coatings used in medical devices must maintain their lubricity and durability post-sterilization.

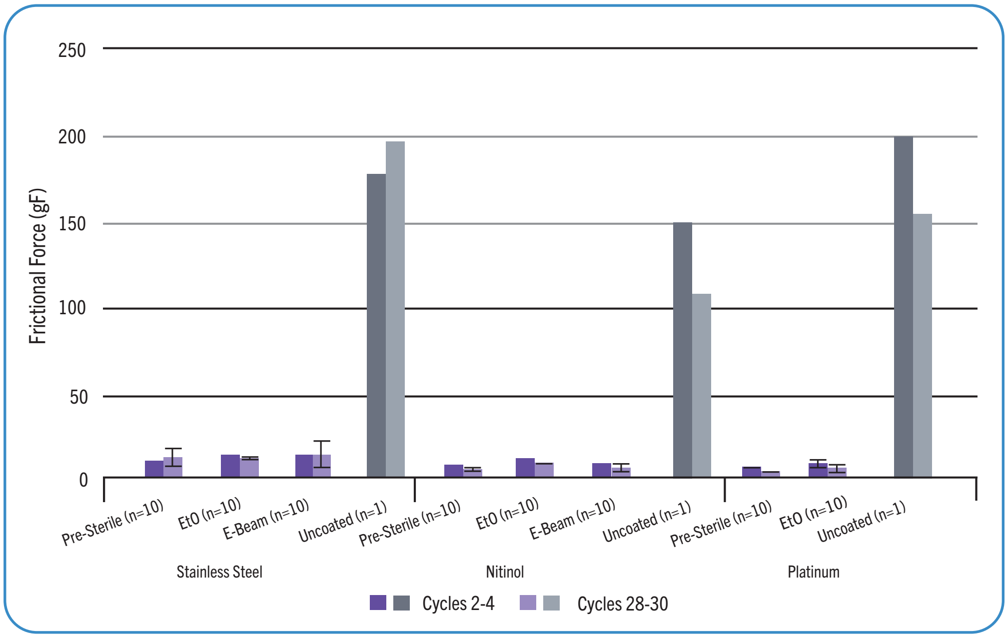
Testing was conducted to evaluate the performance of HYDAK thermal and UV coatings on 0.030" stainless steel, nitinol, and platinum-plated stainless steel wires pre- and post-sterilization using both EtO and E-beam methods.

Figure 5: Frictional Force on 0.030" Thermal-Cured Wires After Sterilization Using Pinch Test



Thermal-cured HYDAK® coatings exhibited minimal changes in lubricity and durability following both sterilization methods. Pinch test results demonstrated that pre-sterilization lubricity was consistently maintained post-EtO and E-beam sterilization on stainless steel and nitinol. Notably, lubricity on platinum substrates showed improvement following EtO sterilization. Across all substrates and sterilization methods, HYDAK thermal coatings achieved at least a 90% reduction in frictional forces compared to uncoated materials.

Figure 6: Frictional Force on 0.030" UV-Cured Wires After Sterilization Using Pinch Test

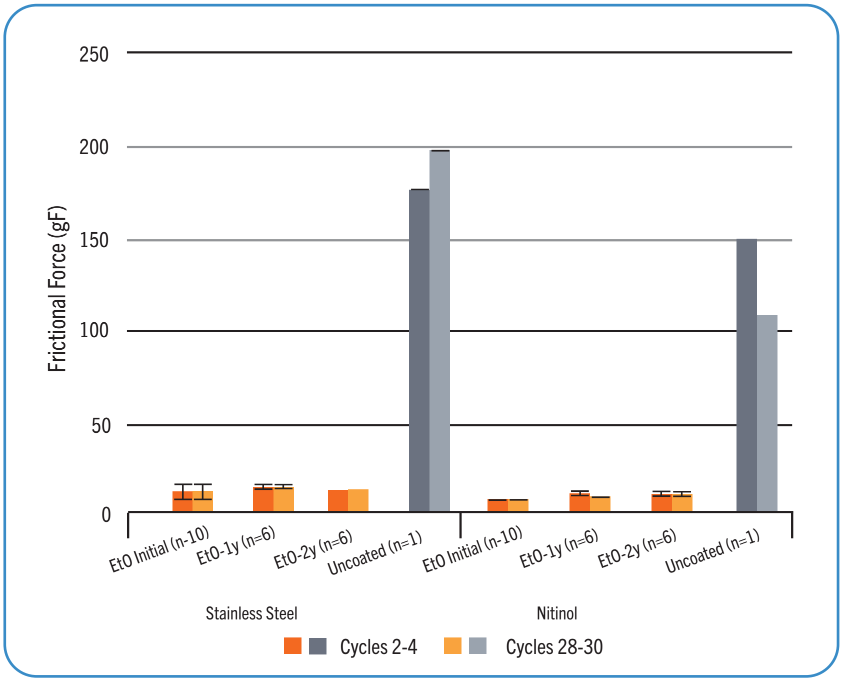


UV-cured HYDAK coatings also demonstrated robust sterilization compatibility, with negligible changes in lubricity and durability post-EtO and E-beam sterilization. Pinch test data revealed that stainless steel, nitinol, and platinum samples retained their pre-sterilization lubricity after both methods. Similar to the thermal coatings, HYDAK UV coatings consistently achieved a minimum 90% reduction in frictional force compared to uncoated samples, regardless of the sterilization method or substrate.

Accelerated Aging

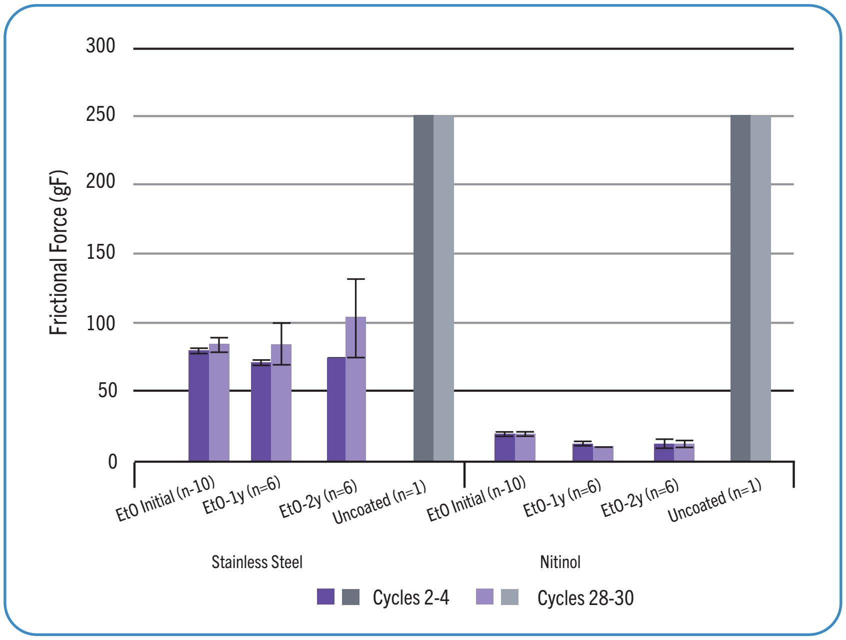
Shelf-life stability is a fundamental requirement for all medical device components to ensure sustained performance and patient safety over time. To assess the long-term stability of HYDAK® coatings, accelerated aging studies were conducted on stainless steel and nitinol substrates. Samples were sterilized with EtO prior to aging and subjected to controlled conditions of 45°C and 50% relative humidity. Evaluations were conducted at intervals equivalent to 1-year and 2-year aging periods. Thermal coatings were tested on 0.030" wires using a pinch test, while UV coatings were evaluated on 0.014” wires using the tortuous path test (Figure 1).

Figure 7: Frictional Force on 0.030" Thermal-Cured Wires After Aging Using Pinch Test



HYDAK thermal-cured coatings displayed exceptional stability through the accelerated aging process. Pinch test results (Figure 7) indicated that pre-aging lubricity levels were preserved across both 1-year and 2-year equivalent aging periods. On both stainless steel and nitinol substrates, thermal coatings consistently achieved a minimum of 90% force reduction compared to uncoated materials, further validating their long-term performance.

Figure 8: Frictional Force on 0.014" UV-Cured Wires After Aging Using Tortuous Path Test



HYDAK UV-cured coatings demonstrated excellent lubricity and durability after 1-year and 2-year equivalent aging periods. Tortuous path test results (Figure 8) showed no significant deterioration in performance on both stainless steel and nitinol substrates. Pre-aging lubricity and durability were maintained throughout the evaluation period, confirming the coatings’ resilience under accelerated aging conditions.

Conclusion

The results of this study confirm that Biocoat's HYDAK® hydrophilic coatings deliver high levels of lubricity and durability on metallic substrates commonly used in medical devices. The performance of these coatings is comparable to, or surpasses, that of PTFE-based coatings, providing a reliable PFAS-free alternative without compromising functionality. Furthermore, HYDAK coatings facilitate production efficiency by eliminating the need for primers or tie-layers during application.

Biocoat's team of coating development engineers is prepared to collaborate with medical device manufacturers to optimize coating formulations and processes tailored to specific device requirements. Our expertise ensures expedited progress through validation and regulatory submission stages. To initiate a project or learn more about HYDAK coatings, contact Biocoat today.

References: 1. McLaren M. Europe's proposed PFAS ban: the next big thing in medical device design and supply. Medical Device Network website. https://www.medicaldevice-network.com/sponsored/europes-proposed-pfas-ban-the-next-big-thing-in-medical-device-design-and-supply/. March 5, 2024. Accessed March 19, 2025. **2.** PFAS & their uses. 3M website. https://pfas.3m.com/pfas_uses. Accessed March 19, 2025.

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