Vactronix Scientific
History, goals and technical capabilities

History

Vactronix Scientific has its roots in the cardiovascular device arena. Julio C. Palmaz, MD (its scientific advisor) is the author of the first commercially approved vascular stent in 1990 and was co-founder of Advanced Bio-prosthetic Surfaces (ABPS) in the late nineties. This company was later licensed to the NDC/Cordis division of Johnson and Johnson. Four years later was re-acquired as Palmaz Scientific and again lately as Vactronix Scientific.

From its inception, this company's mission was to improve upon current cardiovascular device limitations: their surface characteristics and its constituent materials. The first goal aimed to optimize material-host interaction at the molecular level and the second was to enhance the biomechanical properties of current materials used to build these devices.

In the pursuit to develop high performance medical devices, we realized that our new materials surpassed the requirements of the medical device industry. Years of research gave us an understanding of the potential of this technology to be applied in non-medical areas such as in; micromechanics, microelectronics, energy, defense, aerospace, communications, sensors, and other fields. In short, our advanced technology is applicable where high precision and performance is required from metals and alloys in the submicron and nanometer scale. Working in this new field gave us a peek into a future where nano-manufacturing may eventually replace conventional reductive technology.

Limitations of current technology

Current medical device technology has reached a limit in its progress because of the inherent nature of current metals and alloys. This limitation is not evident in devices with large features in the order of one hundred to several hundred microns as used in the heart and large vessels, but it becomes apparent in feature sizes below 60 to 70 microns, such as those used in the brain and below the knee. Large variability in the crystalline structure and significant levels of impurities introduced during reductive (top down) manufacturing, degrades the mechanical characteristics and alters the physical chemical properties. When trying to make very small features, high strength metallic products cannot be manufactured reliably because bulk material defects such as pores, cracks, inclusions, and impurity deposits at grain boundaries cause structural failures. High resolution tooling such as femtosecond laser machines cannot realize their full capabilities creating submicroscopic features using current materials. This is because their grain size and shape variability and intergranular impurities may be larger than the machine resolution limit. This is why current metallic foils, micro tubing, wire and other wrought stock materials are inadequate for making devices requiring microscopic features.

Alternative materials for high resolution manufacturing

High performance metals such as Titanium and Tantalum and alloys such as stainless steel 316L, Elgiloy (Cobalt Chrome) and Nitinol, can be used to create highly pure substances from bottom up, atom-by-atom layer build-up. This is possible by using physical vapor deposition (or PVD). A donor source provides metal ions that can be activated in a high energy plasma. By means of a combination of high vacuum, properly engineered magnetic field, high temperature, voltage bias and heavy inert gas drivers, the donor material can be deposited and grown in a time-dependent manner. Manipulation of the PVD parameters allows control of grain size, orientation and homogeneity, and eliminates grain boundary deposits of foreign contaminants. Thus, highly coherent, high purity materials can be fabricated to a highly refined state, eliminating dozens of manufacturing steps of machining and finishing to manufacture a final product. This methodology is performed in a clean room environment, using computer-driven algorithms via PLC's. The result is a highly automated manufacturing sequence in a clean and physically reduced environment, optimal for highly confidential and security-controlled operations.

Development and testing of novel materials

This novel manufacturing method represents a very fast way to develop new alloys. Changing the percentual composition of an alloy or introducing new components (doping) into a known alloy is readily done by changing the donor components. In a matter of days, rather than months, samples of new alloys can be available for performance testing, compositional analysis and microscopic evaluation. This task is performed entirely in our facility using minimal space and human resources. Vactronix has all the equipment necessary to characterize and test a new material: Scanning electron microscopy and EDS, metallurgical optical microscopy, stress-strain testing, strength limit testing, differential scanning calorimetry, chronic fatigue testing, micro-CT measurements, and surface energy and topographical analysis.

We can create structured materials such as ply-metals to enhance or supplement physical characteristics of known materials such as strength, elastic behavior or radiopacity. Likewise, we can in principle create composite materials by combining metals and ceramics, polymers, oxides or other non-metallic materials. Also, we can create spaces in the thickness of PVD materials to act as deposits for slow release of a substance or an embedment with functional capabilities.

Design and development of PVD equipment

An important aspect of our capabilities is the design of PVD equipment suited to fulfill the need of a particular application. From the early single-substrate PVD to our latest planetary multi-mandrel equipment we have developed ten different iterations of PVD equipment. The latest machines have batch production capability in clean room environment, are substantially smaller compared to the early machines and are PLC controlled, significantly reducing operator intervention. This unique hollow cathode reactor design allows for deposition of three-dimensional structures, such as tubes or net shape balloons. At Vactronix, we have the knowhow and capability to design and fabricate PVD equipment custom-suited for a variety of tasks. These capabilities span from industrial design and blueprinting to vacuum and electronic components manufacturing.

What do medical devices and electronic and aerospace components have in common?

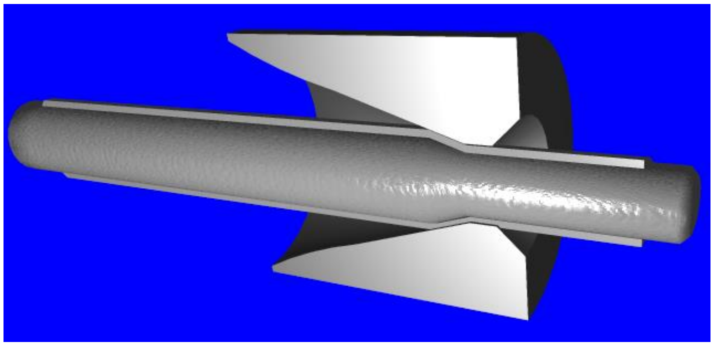
Implantable cardiovascular devices are made of high-performance alloys able to withstand high mechanical loads and resist fatigue failure with the lowest bulk possible. Also, these medical devices must function in chemically hostile environments where corrosion threatens their mechanical integrity. Purity of the constituent materials is essential to ensure physical-chemical homogeneity throughout the surface exposed to cell colonization. This allows consistent and repeatable tissue response from point to point in the same device and from patient to patient with devices of the same type. Large variability in crystalline structure and the presence of residual industrial contaminants between crystals creates conditions for variable tissue response and unpredictable inflammatory reaction. These limitations are evident when any metal stock is worked to very small dimensions to make thin foil, wire and tubing which result in the development of pores, large deposits of salts and glass from successive cycles of cold working and annealing. High pressure lubricants containing aliphatic hydrocarbon compounds, halogens, sulfur, phosphor, and PDMS (silicones) turn into carbonaceous deposits, glass and salt pools.

Excessive tissue buildup results in loss of lumen and decreased flow. Poor or absent tissue buildup may result in clot formation and sudden occlusion. Either condition at opposite ends of the spectrum represent a device failure. There is also a link between strut fractures and lumen loss.

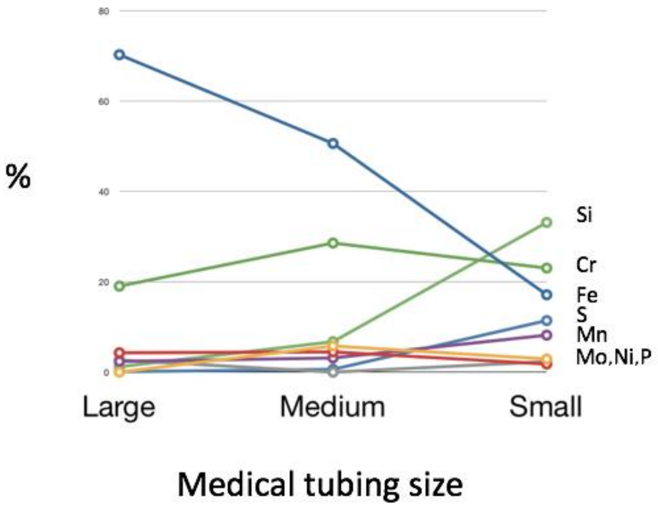
The performance of many electronic components depends on purity of the material and robustness as well as tolerance effects. Charge distribution across conductive layers in a capacitor and the shape and size of the far field in portable communications gear antennas depend on point to point homogeneity and coherence of the metal structure in much the same way medical devices do. Conductive layers in capacitors suffer from discontinuities in the physical structure and chemical composition. These cause irregular charge distribution and current leaks, limiting the total charge capacity. Since the charge density depends on the number of layers in a given volume, the limiting factor in the charge capacity is the thickness of the layers. With current technology, the thinner the layer, the more prone the layer is to current leaks. Conductive capacitor layers are usually made of cold rolled foil. The thickness of the layers is limited by the integrity of the layer. Alternatively, very thin layers can be obtained by sputter deposition of conductive material. Low energy plasma deposition has been employed to produce thin films; however, the coherence of the material is poor with this technique as it is an inherent limiting factor from the low energies used. Poor coherence in a material manifests in high porosity, hence current leaks. Also, it makes the material brittle and therefore not functionally stable under stress. In contrast, high energy deposited thin PVD film is highly coherent and pore free at thicknesses in which conventional foil made by rolling will exhibit pores, inclusions, cracks and other discontinuities. It is feasible to make layers thinner than currently used with good material coherence. Therefore, high energy thin PVD film has the potential to allow for a larger number of conductive layers and therefore more charge capacity for a given volume. Also, the high mechanical properties of PVD material coupled with high strength dielectric materials would create capacitors able to withstand high mechanical loads and increased robustness thereby acting as a composite material with high mechanical properties.

PVD compared to conventional wrought metals and alloys

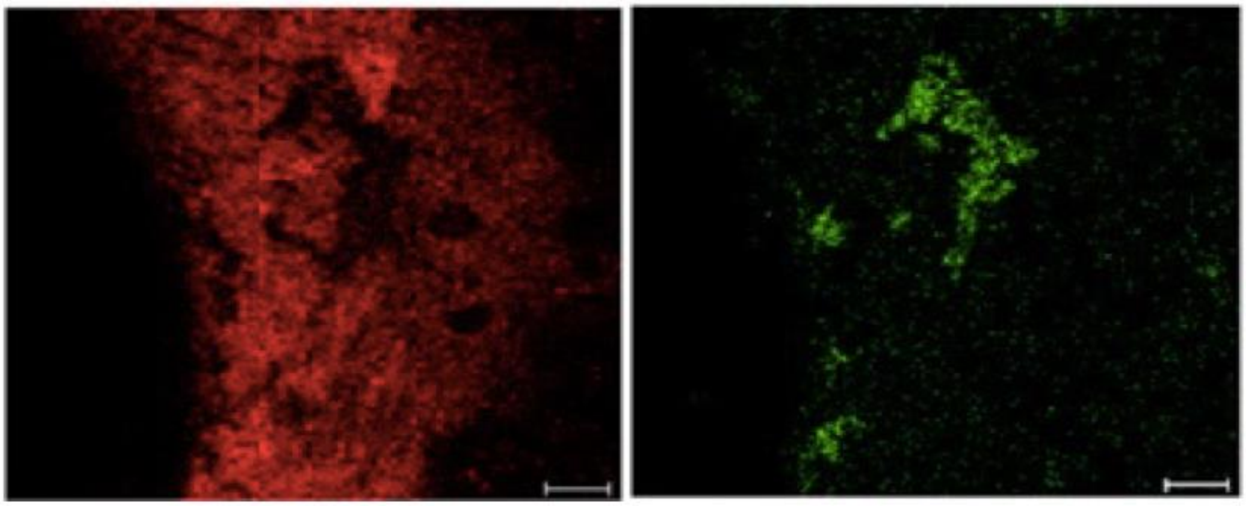
Conventional cold drawn tubing, wire and sheet involves reshaping under high pressure using dies or rollers and high-pressure lubricants.



The process produces incorporation of these lubricants in the bulk of the metal as the material infolds during passage through a die. Sequential steps of drawing and annealing determine that the degree of contaminants in the material increases with the number of steps. Elemental analysis of tubing material made progressively small by repeated steps of cold working and annealing shows a marked increase of lubricant byproducts and tooling residuals.



XPS analysis of the atomic composition of freshly cracked surface of medical grade stainless steel 316L tubing of 12, 6 and 2mm diameters. The marked increase in Silicon and Sulfur in the 2mm tubing compared to larger diameter tubing indicates increased deposits of glass as residual from PDMS and Sulfur from the high-pressure lubricant oils. The drop in Fe and Cr indicate substantial replacement of the original alloy constituents by contaminants.



Time of flight secondary ion mass spectrometry (TOF-SIMS) image of a commercial balloon-expandable stent made with conventional tubing and technology. Iron image (left) and Chromium Carbide image (right) of the same spot. This spot is representative of the whole stent and corresponds to a strut in the center of the device. Defects in the iron image correspond to carbide deposits. The measuring bar is 10 µm.

This process of contamination involves degradation of properties, including tensile strength, fatigue resistance, thermal and electrical conductivity, corrosion resistance, and magnetic behavior.

The superior performance of PVD Nitinol (a superelastic alloy of Ni and Ti) is evident comparing strain-stress curves of the PVD vs wrought NiTi.

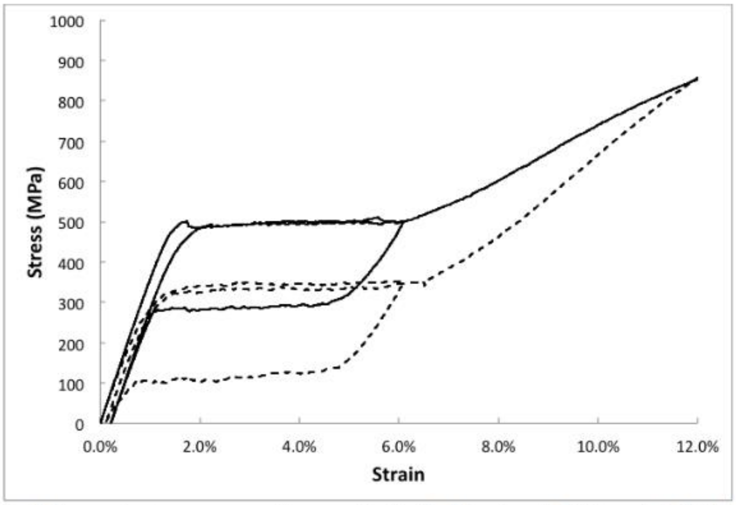
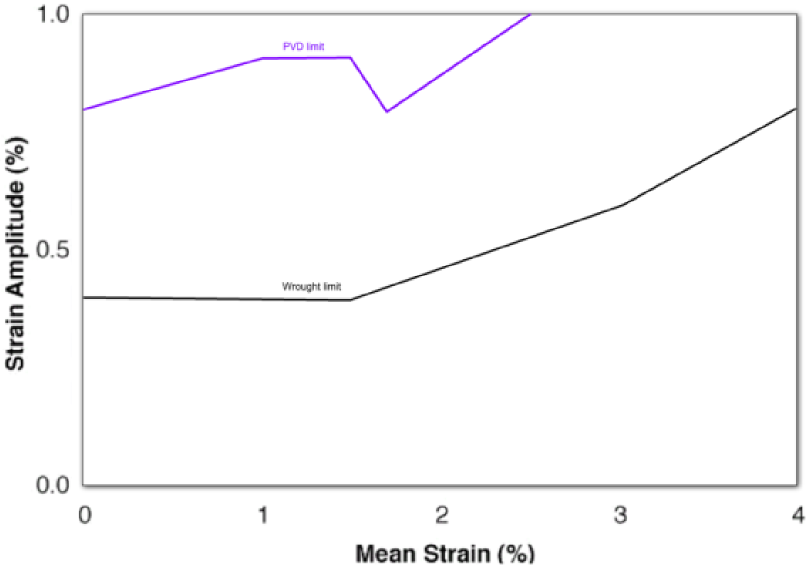


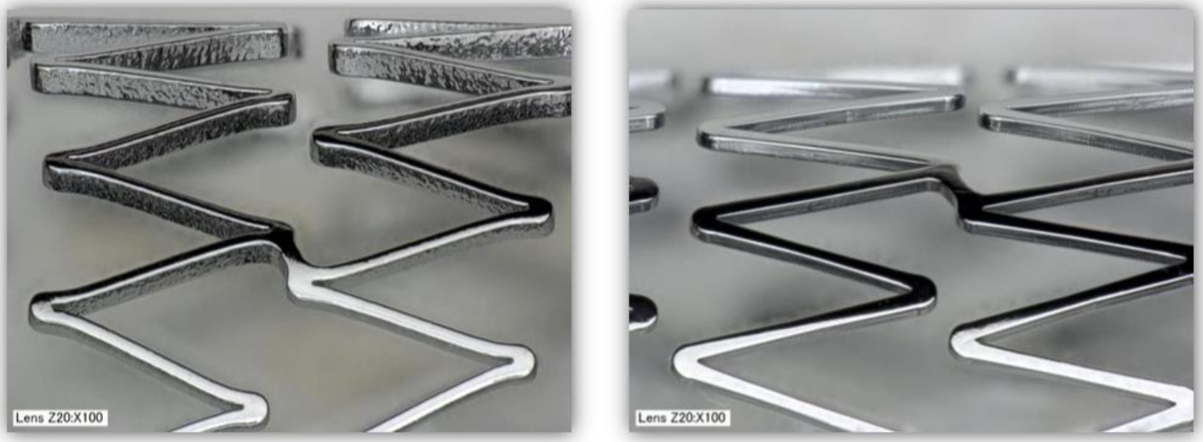
Figure 1: Nominal Stress-strain response of wrought (dashed line) and PVD material (Solid line). Transformation initiates around 0.75% strain for wrought material, at 1.75% strain for PVD material.

Likewise, PVD NiTi is superior to wrought NiTi in fatigue testing by repetitive combined strains.



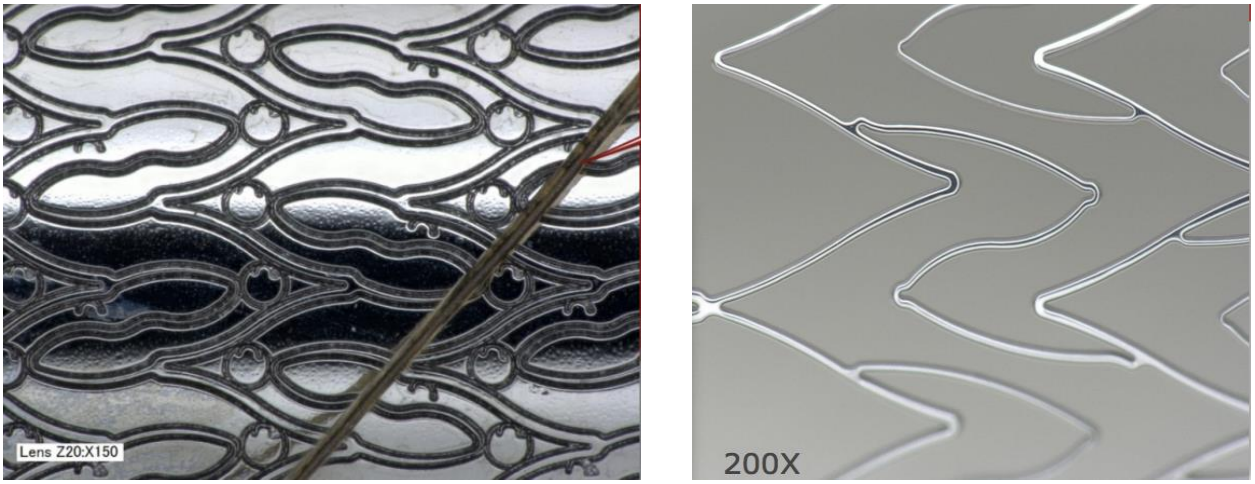
The obvious advantage of superior mechanical performance is the ability to create smaller structures with equivalent performance compared to their bulkier counterparts.

The superior qualities of PVD material can be easily seen by comparing to a device made by employing conventional techniques and materials.

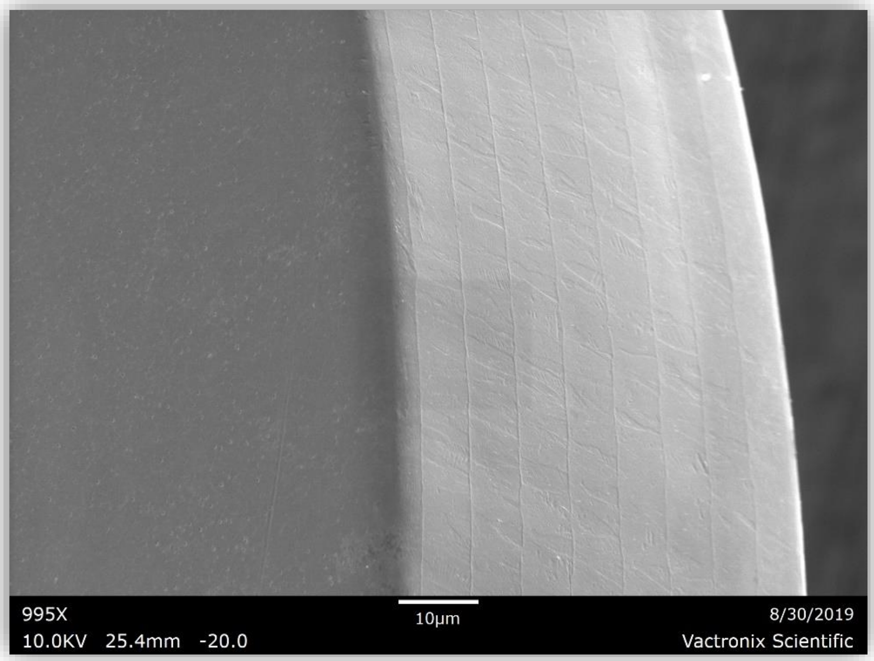


In the example above, the radial strength of a commercial product (on the left) is matched by a PVD device of identical design but half the wall thickness because of the higher mechanical properties of the latter. Also notice the roughness of the commercial finish surface compared with the PVD device shown on the right.

The fine crystal structure of PVD metals compared to wrought metal counterparts is discernible using high resolution microscopy.



PVD materials permit high resolution laser cutting of very small features. On the left there is a pattern of features smaller than a human hair. On the right a high-power microscopic photograph of finely resolved mesh of PVD material showing features as small as 12 microns and superior finish, without defects typically seen in wrought materials at this dimension. These features are smaller than the inclusions observed in commercial wrought Nitinol.



995X SEM image of electropolished PVD Nitinol, 105μm thickness. The ID is surface visible on the left, while the laser ablated wall surface is on the right.

Vactronix Intellectual property

Vactronix has an extensive portfolio of patents, both granted and in progress. This portfolio, amounting to several hundred US and OUS patents is divided in four main types: 1) Patents on PVD material characteristics, mainly including control of heterogeneities and its physical-chemical properties, 2) Patents on PVD equipment and methods of fabricating devices employing PVD, 3) Methods to create engineered surface features of submicron resolution, and 4) Patents on design of medical devices, both implantable and non-implantable. Variants to homogeneous solid materials such as subsurface deposits, and high-resolution surface engineering to influence cell colonization are also incorporated. Furthermore, Vactronix has patents pending in the area of supercapacitors with structural properties.

In conclusion, the PVD materials created at Vactronix have higher levels of purity, high coherence and homogeneity resulting in superior mechanical performance, fatigue and corrosion resistance. The processes developed by Vactronix allow for the creation of highly intricate articles made in only a few simple steps. These materials will define a new standard for fabrication requiring submicroscopic and nanometer tolerance. The bottom-up fabrication of these materials is a practical example of nanotechnology and its potential to replace current conventional technologies in fields as diverse as medicine, electronics, energy, and aerospace.

Entry Façade.

Vactronix is located in the heart of Silicon Valley, with broad access to expertise in vacuum technologies, metallurgy, microelectronics and solar energy as well as readily available technical support

Production PVD Equipment in Cleanroom

At the heart of Vactronix is a clean room class 1000, where the production PVD equipment operates.

Femtosecond Lasers Lab

State of the art femtosecond lasers were custom-designed to create submicroscopic features in PVD materials

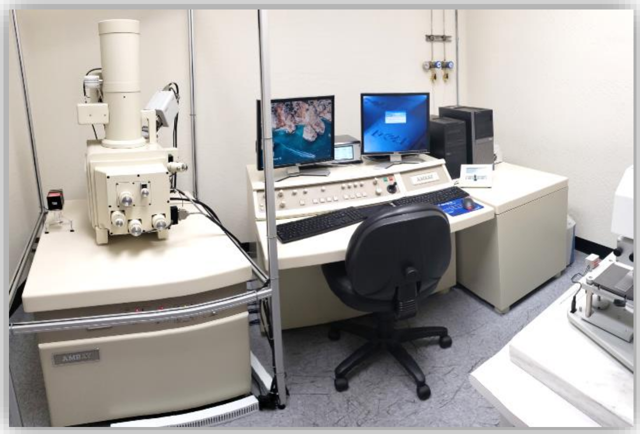
Chemical Processing Lab

This lab is equipped to create a) Highly polished mandrels for PVD deposition. b) Photolithographic micro-engineering of PVD material surfaces. c) Chemical release of PVD deposited materials.

R&D PVD Lab

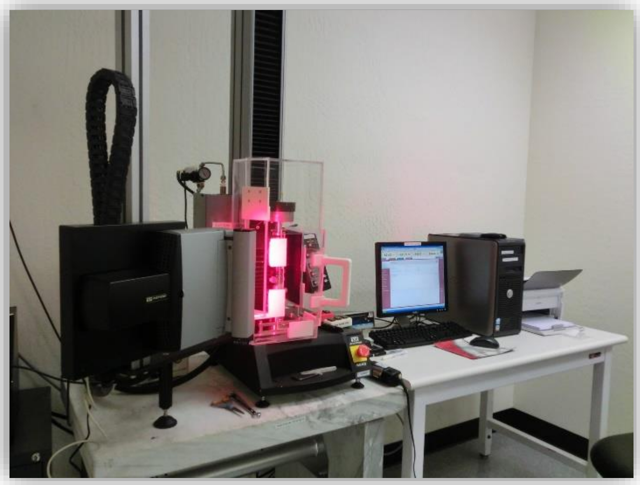
New PVD equipment development and clean assembly of components from our machine shop

Testing and Characterization of Materials



Amray SEM with Elemental Analysis Capability

Differential Scanning Calorimeter with Autosampler



Instron Tensile Tester with Thermal Chamber

Zygo Optical Interferometer

Keyence 3D Digital Microscopes, up to 1000X

Micro-CT 3D measurement System