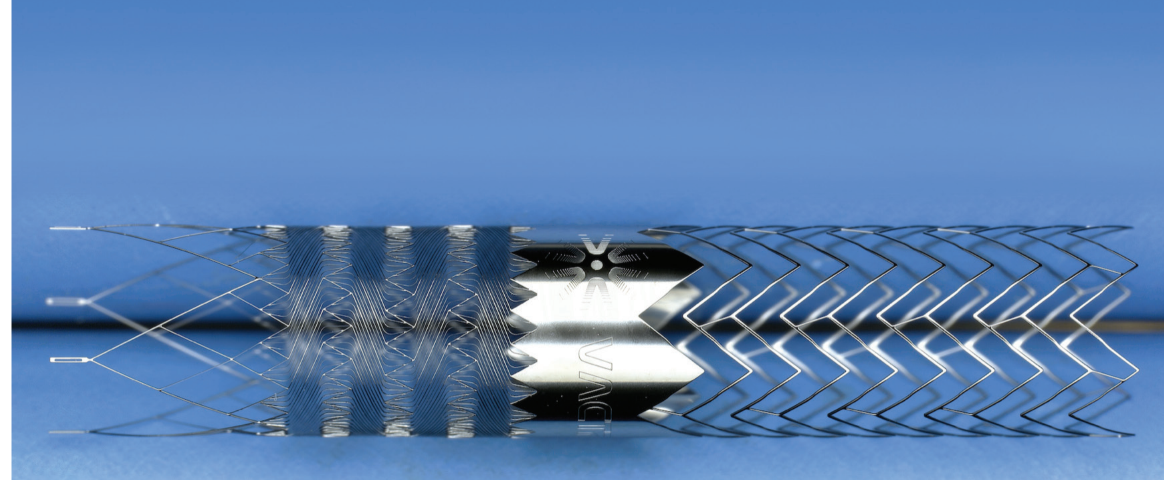
VACTRONIX
SCIENTIFIC

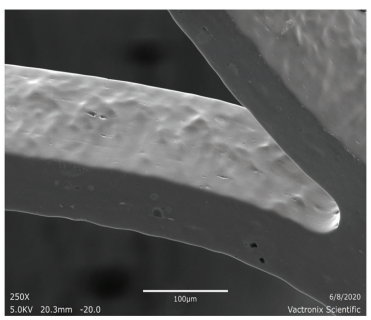
Foundational Technology for Tomorrow's Devices

Vactronix Scientific™ is a material science company with a mature technology platform, changing the way devices from medical to aerospace are designed, fabricated and assimilated.

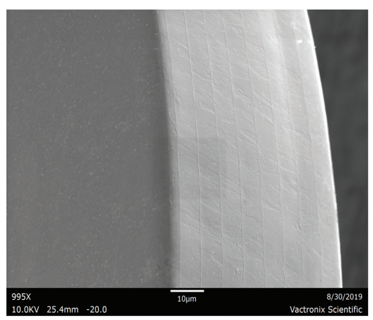


Evolution is Revolution

Current medical device technology has not kept pace with the increasing refinement of the latest interventional methods requiring greater functional capabilities. The reliance on foundry-sourced materials, reductive manufacturing and extensive hand labor makes it impossible to go beyond certain miniaturization limits and maintain tight dimensional and functional tolerances. The inherent limitations become evident when devices made with traditional technologies are pushed into extreme engineering requirements.



SEM image of a **commercial NiTi stent** at 250x



SEM image of a **Vactronix PVD based NiTi stent** at ~1000x

At Vactronix, we have developed powerful technologies based on additive atomic buildup (bottom-up manufacturing) to replace the traditional top-down or reductive manufacturing. This approach allows us to advance bio-mechanical performance to new levels, and to control design and tolerances to micron scale. These objectives are made possible by replacing current conventional wrought alloys by high energy PVD synthetic materials. By controlling point-to-point heterogeneity in the material and its structural arrangement, it is possible to engineer bulk structure and surface features to sub-microscopic levels. These capabilities allow making superior devices with high performance properties. In our laboratories, sophisticated new alloys and materials engineering have pushed performance to unprecedented new levels and have enabled the creation of design geometries not possible using traditional means.

Your ideas. Executed.

Dream it.

Regardless of the size of your design team, Vactronix can quickly on-board engineers to take full advantage of higher resolution fabrication capabilities and higher material properties. Efficient in-house computational analysis, such as FEA, aid mechanical design requirements before the first prototype is even made.

Validate it.

Whether your device is undergoing early bench-top testing in-vitro or undergoing evaluation in an advanced clinical trial, you need a partner who understands your requirements. Our manufacturing efficiently scales to your needs and our ISO13485 provides compatibility and familiarity to your regulatory environment.

Prototype it.

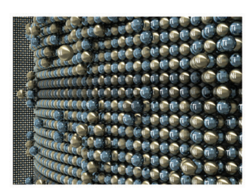
We set a new standard to the term rapid-prototyping. Full vertical integration from the raw material development, characterization, device fabrication, and testing mean iterations happen quickly and efficiently. Ready. Set. Done.

Supply it.

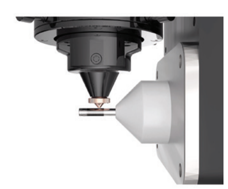
Are you ready to supply the market? We are. Our technology allows seamless and scalable growth at any level — big or small! We can greatly simplify your supply chain and integrate with existing pieces in lockstep.

Vertically Integrated for Rapid Product Development.

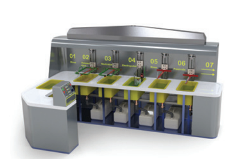
From development of a new alloy to existing ASTM, Vactronix has everything you need to rapidly characterize, design, fabricate, test and validate your next big idea.



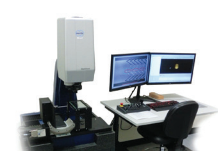
PVD Material Development



Precision Device Fabrication Development



Integrated Device Processing



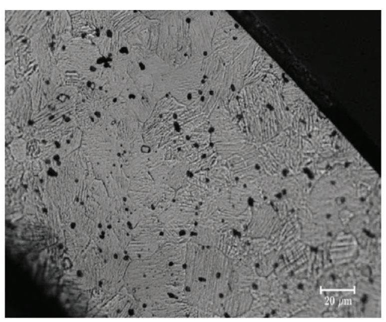
Advanced Testing & Validation

Welcome to next generation PVD.

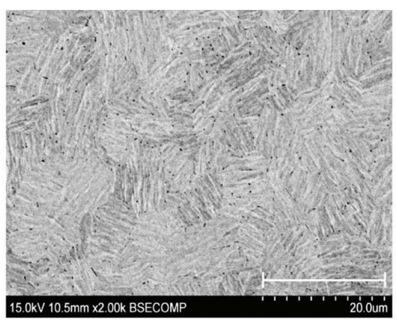
Not just thin, **thick** film.

Wrought vs PVD (Physical Vapor Deposition)

Traditional medical device manufacturing is a multi-step technique that starts by foundry produced wrought materials undergoing hundreds of reductive steps involving die tooling, heating and lubricants. Many of these steps take place in un-clean environments until they reach the stage of the so-called medical tubing and wire. In cleaner spaces like medical device facilities, these materials undergo many steps of laser cutting, abrasive and electropolishing, and heat setting. Most of these steps remove material so that the final product has a small fraction of the initial mass. From the physical-chemistry standpoint, each step along the device manufacturing history leaves a footprint consisting of residual chemicals, structural defects and foreign inclusions. The relevance of these abnormalities depends on the expected mechanical performance and final device dimensions. In general, failure induced by these defects is related to size of the features, the mechanical workload and the corrosion exposure. Highly stressed devices of very small dimensions will be more prone to fail than larger counterparts, hence, the limit these materials and methods have when pursuing miniaturization.



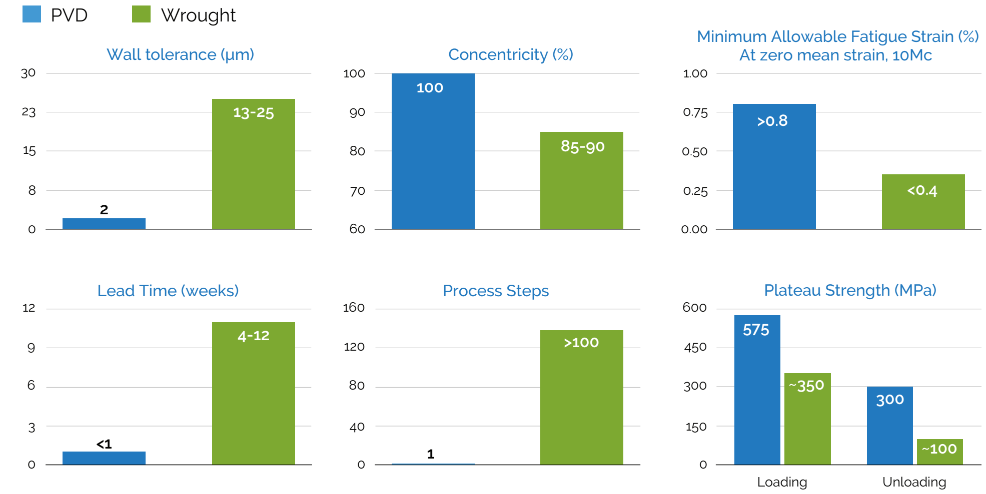
Wrought Nitinol Stent Strut Image
Grain size 20-40µm, mean inclusion size 2,600nm, carbide and oxide inclusions.



PVD Nitinol Stent Strut Grain Level Image
Grain size 2.2µm (note the scale), mean inclusion size 45nm (<half as many), almost entirely carbide inclusions.

By contrast, Vactronix Scientific's patented methodology is based on high vacuum, high energy build-up of alloys from basic donor materials. Elemental metal ions are deposited atom by atom from a plasma onto a substrate which serves as a template for the device in its final shape state. The resulting material is comparatively purer because of the elimination of tooling and manual labor steps. The process is tightly controlled by computer assistance eliminating human error variability. Also, our method parameters can be manipulated to affect crystal size, orientation and arrangement, therfore controlling the bulk microcrystalline structure. The resulting material has increased compositional purity and remarkable metallurgical properties. The inherent homogeneity makes it an ideal substrate for high-definition laser cutting. The small crystal size allows for smaller features that are metallurgically sound. Laser ablation beam control allows single digit micron tolerances that are difficult or impossible to maintain employing wrought materials. The following section will compare VS PVD and wrought materials to illustrate the enhanced capabilities of this novel technology.

Nitinol Tubing Process Comparison



Nitinol Component Process Comparison

Wrought Processing

Tube fabrication from 1.0-1.3" bar ~130 steps → Laser cutting → Stress relief → Diamond or slurry hone → Expansion Step 1 → Expansion Step 2 → Expansion Step 3 → Microblasting → Chemical Etch → Electropolish

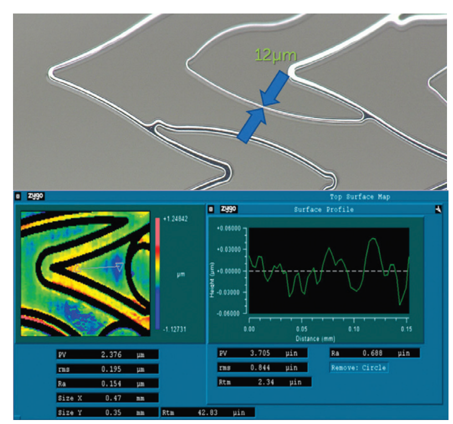
PVD Processing

Vapor Deposition 1 step, PLC Controlled → Laser ablation → Electropolish → Release Etch

Vactronix Scientific's unique processing allows us to simplify the multi-step traditional manufacturing to only a few steps at a fraction of the time involved. By eliminating the multiple steps of heat setting and abrasive/corrosive polishing typically involved in vascular device manufacturing, this technology simplifies fabrication eliminating hand labor and reduces environmentally sensitive finish processes.

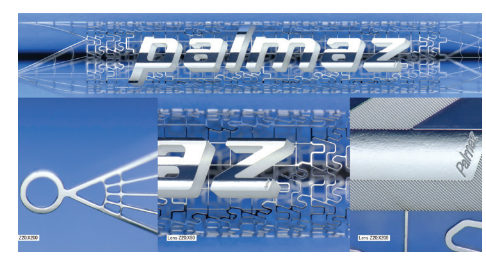
Excellent EP Finish

Combination of laser ablation and on-substrate EP process yields a new standard.

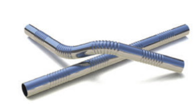


Holding ± single digit microns on specifications and surface roughness values under 1 µin is routine production at Vactronix Scientific every day.

We do complicated



This capabilities demo part incorporates millimeter and micron features all in one monolithic design. This level of detail is impossible using conventional fabrication methods. Have a challenging design? Bring it on.

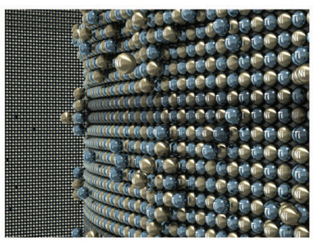


Because Vactronix's technology is based on true 3D PVD, we are not limited to simple geometries. We routinely work with complex 3D shapes. Finally, a process that can meet your imagination.

Full Service R&D and Fabrication

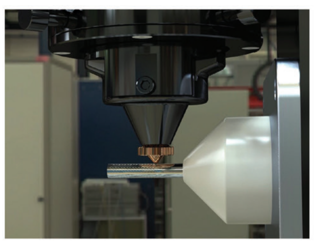
Working with Vactronix is easy. We offer a complete suite of capabilities that allow customers to quickly maximize our unique material and process capabilities via contracted R&D efforts. Throughout development, we work to transition the customer to a highly scalable and repeatable component manufacturing that enhances value. The following is a basic overview of standard services and capabilities we can offer your team.

Vactronix Core Technology Areas



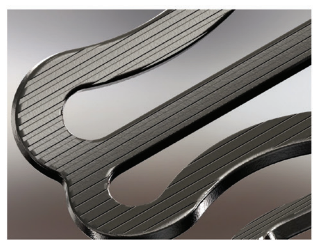
Physical Vapor Deposition (PVD)

Next generation devices need next generation materials. Vactronix's proprietary high-energy 3D PVD technology delivers materials with dramatically higher performance in every category. Scalable. Repeatable. Cost-Effective. Flexible. Superior.



Component Processing

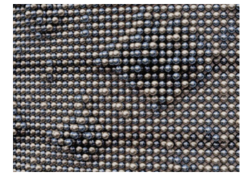
Vactronix utilizes the latest "cutting-edge" femtosecond lasers and adds its own proprietary technology to hold the tightest tolerances in the industry. Because deposition occurs on a stable substrate, we routinely hold and easily validate to single digit micron scale specifications.
We love complicated.



Engineered Surfaces

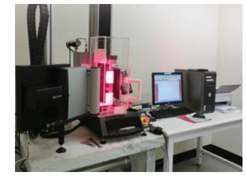
When you can control surface heterogeneities to this level, devices are begging for unique engineered surface topologies. With a full suite of ablation, chemical and lithography capabilities in house, your imagination is the only limitation.

Rapid Development Toolbox



PVD Material Fabrication by High Energy 3D Deposition

- Target and substrate preparation
- Tubular and custom net shape chamber configurations
- PVD sputtering of binary Nitinol (per ASTM-F2063 & F-2633) and ternary Nitinol alloys, plus other metallic materials.

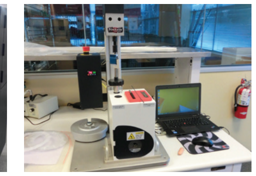


Material Characterization Capabilities

- Tensile mechanical properties (per ASTM F-2516 with thermal chamber)
- Transformation Temperature by BFR (per ASTM F-2182) or DSC (per ASTM F-2004)
- Metallurgical preparation and analysis - diamond saw, polisher, potting apparatus
- FE-SEM with SED, BSED, & EDS
- 3D optical imaging up to 1000x magnification
- Surface characterization and engineered surface treatment
  - Patented engineered surface technologies
  - Optical interferometer for surface roughness and film thickness
  - Sessile drop surface tension measurement
  - Potentiodynamic corrosion testing per ASTM F-2129

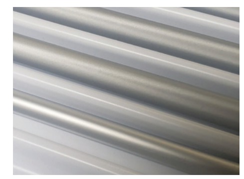
Precision Measurements

- Precision, micron-scale dimensional measurement by optical microscopy
- 0.1µm resolution drop gage
- 5-axis automated stent measurement
- Micro-CT with sub-micron voxel resolution
- Laser micrometers



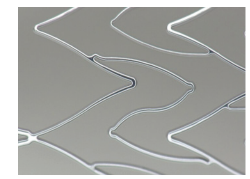
Device Testing

- Flow model with blood analog
- Catheter push force measurement
- Iris crimpers/loaders - several
- Radial force measurement up to 120mm length x 16mm diameter



Novel Alloy Development

- In-situ alloying during PVD
- Radiopaque ternary alloys and coatings
- Can work beyond the limitations of foundry based process
- Overnight rapid iterations driven by characterization
- Dramatically lower cost

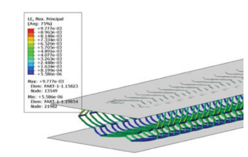


Device Fabrication

- 2-axis laser ablation
- Heat treatment or shape-setting up to 1250°F/677°C and up to 16"x30"
- Polymer and metallic coatings
- Electropolishing
- Chemical passivation

Equipment Design & Build

- Mechanical, electrical, and software engineering
- Partial machine shop



Device Design/Optimization Assistance

- Mechanical design and FEA (finite element analysis)
- Rapid prototyping including latest generation FDM 3D printers

bsi.

Certificate of Registration

By Royal Charter

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Vactronix Scientific
5005 Brandin Court
Fremont
California
94538
USA

Holds Certificate No: **FM 676051**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Research and manufacture of PVD-based components using nickel-titanium alloy for medical purpose.

For and on behalf of BSI: Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-04-11
Latest Revision Date: 2021-02-11

Effective Date: 2021-04-11
Expiry Date: 2024-04-10

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...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Patent Protected

With over 350 patents and pending applications across 18 countries, we own our space. Vactronix Scientific continues to develop and enhance new capabilities every day. Our approachable R&D and supply agreements allow our customers to develop and own their device IP while benefitting from our worldwide patent protected processes.

Quality Management System

- Electronic document control and quality management system
- QAD MRP (manufacturing resource planning) system
- ISO 13485:2016 registration through BSI
- Quality policy from QSM-00001

Corporate HQ
4725 College Park, Suite 200
San Antonio, TX 78249

R&D | Manufacturing
5005 Brandin Ct.
Fremont, CA 94538

510-358-8400

vactronixscientific.com

Words we live by.

Vactronix Scientific LLC is a material science company with a mature technology platform that changes the way implantable prosthetic devices are fabricated and ultimately assimilated by the human body. The company's initial products are focused on intravascular stent technology with future product potential in orthopedic, cosmetic and other medical specialties, or non-medical products that may benefit from the Company's technology platform.

Through innovation, teamwork and operational excellence, Vactronix Scientific is committed to delivering the highest quality medical devices that meet or exceed customer expectations.

Vactronix Scientific Quality Statement

The Company and its employees are committed to the following quality principles:

- **Quality is Customer-focused**—we will provide superior products and services that customers (within and outside our company) want and that consistently provide value that customers expect.
- **Quality is Prevention**—we will work together and with our suppliers and our customers to design and maintain excellence in our products and business processes.
- **Quality is QMS Effectiveness**—we will evaluate our effectiveness in who we are and what we do, making our efforts easier and their results better.
- **Quality is Timely**– we are committed to maintaining compliance with ISO and FDA standards and to responding to any changes in those regulations in a timely fashion.
- **Quality is Scalable**– we are committed to inventing novel, disruptive technologies as well as ensuring that these technologies are scalable, repeatable, and cost effective. These qualities are necessary for adoption of our new technologies.