

THICK FILM PVD-BASED MEDICAL DEVICE COMPONENTS

Using a physical vapor deposition process to manufacture medical device components reduces post-processing time and improves materials properties.

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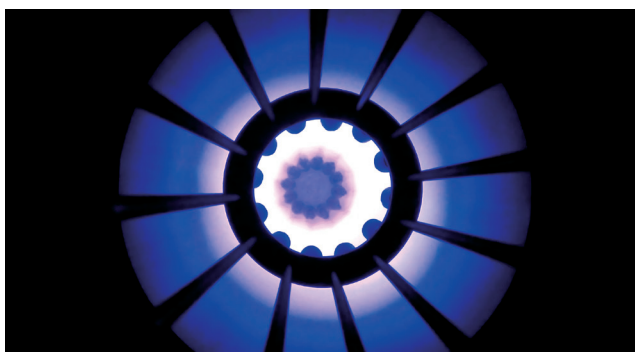


Fig. 1 — Plasma in a hollow cathode PVD reactor.

Physical vapor deposition (PVD) is used to additively fabricate intermediate materials at the atomic scale.

These materials can be further processed into finished device components. This is a relatively new development for medical devices compared to the traditional reductive methods typically used today. PVD fabrication offers advantages in dimensional tolerance control, material properties, surface finishes, and the range of feature sizes. It can also reduce the processing steps needed to achieve a finished device. Although PVD can be used to process metals, ceramics, and polymeric materials, this article will focus on metallic sputter deposition. Likewise, it will not focus on PVD coatings or other vapor deposition processes, such as chemical vapor deposition or reactive sputtering. The PVD processes used for device components differs from the PVD processes used in electronics in that the primary function is mechanical and the films are significantly thicker. These thick films can be upwards of 350 μm wall thickness.

THE PVD PROCESS

It's helpful to begin with some background on the PVD process^[1,2] itself. In this high energy vacuum transport

process, donor material ions from the sputter target are dislodged by the high energy nuclei of an inert gas plasma that strikes the target (Fig. 1). These free donor ions are then attracted onto a sacrificial substrate by an electric field where they reassemble into a new shape, based on the shape of the substrate. Figure 2 illustrates this mechanism. The substrates can be planar, tubular shapes, or fully three dimensional. The material is built up atom by atom until the final desired thickness is achieved. This is similar to the transport mechanism of electroplating, albeit in a plasma state, rather than in liquid. There are different PVD machine chamber configurations, including planar and cylindrical constructions, each producing preferred material formats.

The PVD material structure is a function of the processing parameters, and thus the resulting material can be amorphous or crystalline, depending upon the processing parameters^[3]. PVD typically produces crystalline films with final properties direct from the deposition by tuning these process parameters. This intermediate material can then be patterned, typically employing laser ablation or photolithography^[4]. The components can be electropolished while still on the substrate, if desired. Finally, the substrate material is removed, resulting in a discrete component. This

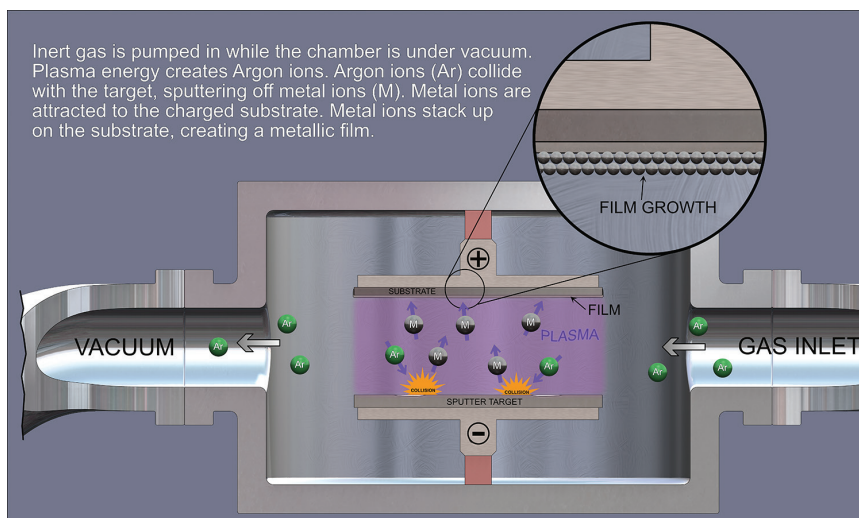


Fig. 2 — Atomistic view of film growth mechanism.

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free component can be further processed by heat treating, coating, electropolishing, or other typical post-processing.

PROPERTIES AND BENEFITS

PVD materials typically have finer grains, higher tensile properties, higher purity, improved biocompatibility, smooth finishes, and higher fatigue and corrosion resistance than their wrought counterparts. For example, grain sizes in PVD Nitinol are typically an order of magnitude smaller with inclusion sizes two orders lower than traditional wrought Nitinol. Figure 3 compares tensile curves of binary Nitinol produced by PVD and wrought processes, and includes data for a PVD NiTiCo alloy as well. Because of the stable substrate, these intermediate materials can be grown at their net shape, for example at the expanded diameter of a finished stent. Micron-to-millimeter sized features can be created repeatably due to the support from the underlying substrate. The fine finishes allow for incorporation of engineered surface features. An example of these feature sets is shown in Fig. 4. The substrate support also allows for long device fabrication without cantilever effects. This reduces

post-processing and retains the higher materials properties. This process allows designers new freedoms that are not practical or possible using current reductive wrought material processing. Ternary alloys can add inherent radiopacity or even higher strength. Predictable feature sizes and finishes enable integration of additional functionality.

Since the PVD process does not use drawing dies, or other wearable tooling, it is easy to produce ternary Nitinol alloy materials that are difficult to work using reductive technology. Alloys can be quickly fabricated by using doping or co-sputtering^[5] during the deposition process, allowing for rapid alloy development. The PVD process is run by an industrial computer and does not require operator intervention, other than to load and unload a magazine of substrates. Final microstructure, properties, and dimensions are controlled by the deposition software recipe and can be easily manipulated. The minimal labor content and reduced processing steps makes PVD devices cost competitive with wrought processing over some range of sizes. Since the only prerequisite for a new size or configuration is the substrates, new sizes and shapes can be made very quickly,

speeding product development timelines. Intricate substrates can even be produced utilizing 3D printing.

FORMATS AND APPLICATIONS

There are various formats of PVD films available and many more that are possible, given the need. Flat sheet discs and cylindrical tubing are the most commonly available formats. Non-cylindrical or 3D net shape films are less common. Layered films of various materials are also less common. For instance, a tri-layer sandwich film of Nitinol-Tantalum-Nitinol shows excellent full device radiopacity without the need for adding radiopaque markers. Flat sheets of 4 to 6-in. diameters are produced using planar chambers, while cylindrical chambers can produce tubing from 1 to 10 mm up to 12-in. in length, up to a dozen or more per batch on a carousel. Planar chambers

can produce cylindrical films as well, using substrates spinning on their long axes during sputtering. In the range of a few microns to 150 μm thickness, the devices are normally cost-competitive with traditional processing. Applications where the fabrication is not possible or practical traditionally, may be economically viable using a PVD-based approach. Other sizes are possible by means of reduced batch throughput or by developing custom chambers. For example, Nitinol PVD tubing up to 25 mm has been deposited. Films of superelastic (SE) or shape memory (SM) Nitinol, SE NiTiCo, SE NiTiPt, SM NiTiCu, 316 SST, Mg and Fe resorbable alloys, NiFe, NiTiMn, CuNiMg, and elemental films of Al, Ti,

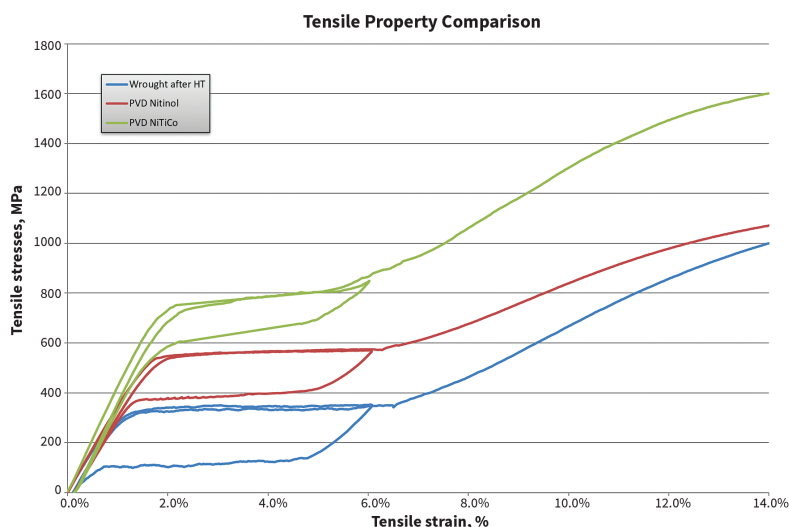


Fig. 3 — Tensile curves at 37°C: Blue represents wrought binary Nitinol device properties; red indicates binary PVD Nitinol; and green is a PVD NiTiCo alloy.

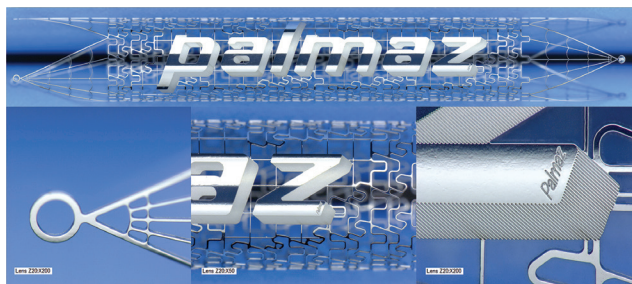


Fig. 4 — PVD demonstration sample showing micron and millimeter sized features with engineered surface texture. Sample diameter is 6.2 mm for scale.

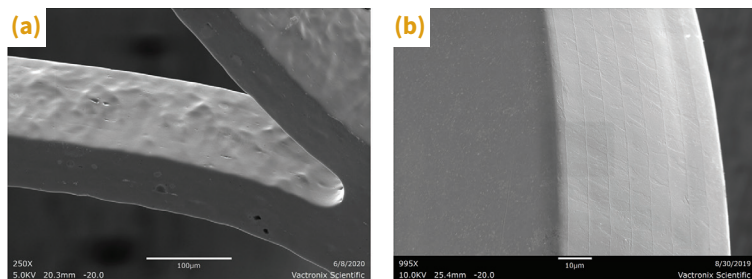


Fig. 5 — (a) SEM image of a commercial NiTi stent at 250x; (b) SEM image of a Vactronix PVD-based NiTi stent at ~1000x.

Cr, Cu, Mo, Ag, Au, Ta, Pt, Au, and Mo are produced using this method. There are a couple of radiopaque superelastic alloys in development.

A frequent request for PVD technology is to evolve an existing approved self-expanding superelastic Nitinol stent design by making the contemporary device pattern at approximately half of the wall thickness, while retaining radial force and improving fatigue resistance (Fig. 5). The higher tensile plateaus and fatigue resistant microstructure allow for this end. Often the delivery system profile can be reduced as an added benefit.

Other enabling devices use PVD for sensor or active device applications where accuracy and predictable performance are imperative. One approved medical device example of a critical Nitinol application is a cataract capsulotomy device used in ophthalmic surgery. An intricate and precise Nitinol ring, assembled into a silicone suction cup and attached to a handle, is connected to a pair of electrical leads that pass through the assembly and terminate to a power supply. The thin Nitinol ring is able to pass through a narrow slit, reopening itself and the surrounding suction cup once inside the eye. When energized using an electric pulse that passes through the circumference of the ring, the lens tissue is cut in a centralized circle by resistive heating. The suction cup fixes the position of the ring on the eye during the cut. This allows the lens to be removed and replaced by an artificial or cadaveric lens. In order to operate without

fault, the ring component requires a wall thickness tolerance and feature tolerances of single digit microns. Although the ring is very thin, it needs to have a high recovery force to open the folded suction cup. It also needs to be cost effective and scalable to high volumes in order to meet procedure reimbursement limits.

Regulatory bodies in the U.S. and worldwide are familiar with PVD Nitinol devices. Although these materials are currently used for approved implant and non-implant devices, there are potential applications in automotive, power, defense, microelectromechanical systems, and aerospace applications where similar needs for accurate, predictable, high-performance materials exist in the relevant size ranges.

~SMST

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