Medikote™

PVD COATING TECHNOLOGY

Improving The Products
That Improve Our Lives

RICHTER PRECISION INC.

an ISO 13485 Certified Company

RICHTER PRECISION INC.

Richter Precision, Inc. is the largest independently owned Physical Vapor Deposition (PVD) coating company in North America. During more than 35 years of operation, we have always placed a special emphasis on our work for the medical device industry. As part of our continuing dedication to supplying high quality thin-films to this industry, Richter Precision, Inc. has created our Medikote™ PVD coating process.

PVD COATING

What Is PVD Coating?

Physical Vapor Deposition (PVD) is a term used to describe a family of vacuum coating processes. The most common of these PVD coating processes are evaporation (typically using cathodic arc or electron beam sources), and sputtering (using magnetic enhanced sources or "magnetrons", cylindrical or hollow cathode sources). All parts are processed in a vacuum chamber at working pressure (typically 10^{-2} to 10^{-4} mbar) and generally involve bombardment of the substrate to be coated with energetic positively charged ions during the coating process to promote high film density. Additionally, reactive gases such as nitrogen, acetylene or oxygen may be introduced into the vacuum chamber during metal deposition to create various compound coating compositions. The result is a very strong bond between the coating and the substrate and tailored physical, structural and tribological properties of the film.

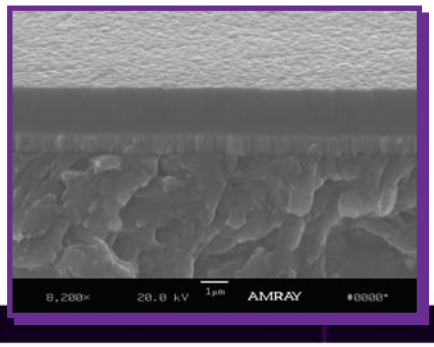
Characteristics of the PVD Coating Process:

- Performed in a vacuum (10^{-2} – 10^{-4} mbar)
- Relatively low process temperature (320°-800°F)
- Line of sight coating deposition
- Coating exhibits a physical bond to the substrate
- Average thickness: 2-5 µm, or .00008-.0002"
- Average chamber cycle time is 4-6 hours, depending upon film characteristics & load density
- Suitable for a wide range of common medical substrates:
  15-5 SS, 13-8 SS, 17-4 SS, 420 SS, 455 SS, 465 SS, Titanium, Cobalt Chromium, etc.
- Ideal for components with close tolerances (+/-.0001" is appropriate)
- No post-coating heat-treating is required
- Excellent for sharp edges: no excessive coating build-up
- PVD will replicate existing surface finishes: a high polish will be maintained

Quality Management System

Since a robust Quality Management System is a key factor to our success in the medical device market, we are pleased to be the first PVD coating facility in North America to have achieved ISO 13485 certification. This effort was premised on our policy of exceeding our customers' expectations and requirements.

The ISO 13485 certified Quality Management System that we have put into place also complies with Quality System Regulation 21 CFR Part 820 of the FDA. Furthermore, most of our coatings are ISO 10993 compliant by 3rd Party.



Our on-site engineering staff, metallurgical and thin-film analysis laboratory, machine shop and PVD processing, in addition to our compliance with ISO 14971 (Risk Assessment), allow us to achieve an unparalleled level of production efficiency and quality. The synergy that exists between our design, manufacturing, production and quality departments means that our customers receive the highest levels of service and quality.

MEDIKOTE ™ PVD COATING

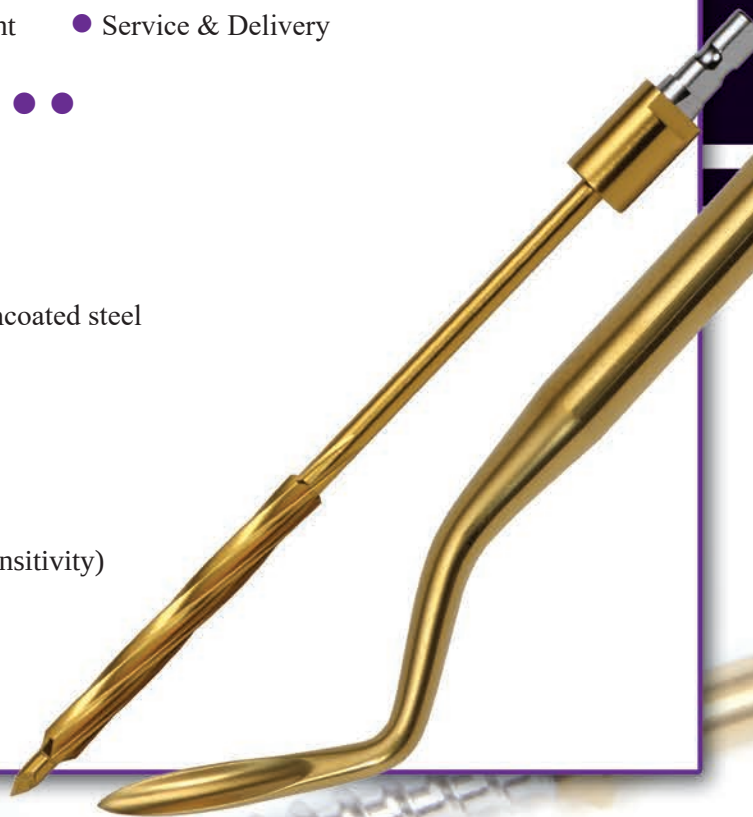
What Is Medikote™ PVD Coating

Medikote™ is a specialized PVD coating process specifically designed to meet the stringent quality requirements of the medical component device manufacturing industry. Medikote™ creates high quality thin-films with excellent hardness, lubricity and adhesion characteristics. Special emphasis is placed on:

- Traceability
- Critical Process Validation
- Frozen Process Control
- Continuous Improvement
- Inspection / Certification
- Service & Delivery

Benefits Of Using Medikote™ PVD Coating

- Biocompatibility
  1. MEM Elution Cytotoxicity Test: Grade 0, non-toxic
  2. Non-mutagenic, non-hemolytic, non-pyrogenic
- Reduced Friction
  1. Coefficient of Friction: From 0.10 to 0.35 versus 0.7 for uncoated steel
  2. Can prevent seizure of non-lubricated parts
- Improved Wear Resistance
  1. Sharp cutting edge retention
  2. Prevents material erosion is high wear areas
- Barrier Layer
  1. Creates inert barrier (example: protection against nickel sensitivity)
  2. Dielectric properties (Medikote™ C11 DLC only)
- Aesthetic Considerations
  1. Identification purposes
  2. Create a distinctive look within a market



Medikote™ PVD Coating Processes

Trade Name	Composition	Color	Micro-Hardness (HV)	Coefficient of Friction
Medikote™ C	TiN	Gold	2300-2500	0.35
Medikote™ C3	CrN	Silver	2000-2200	0.35
Medikote™ C5	TiN / TiCN	Bronze/Gray	2800-3200	0.30
Medikote™ C6	AlTiN	Violet/Black	3000-3400	0.35
Medikote™ C6B	TiAlN	Copper/Bronze	3000-3200	0.4
Medikote™ C8	ZrN	Pale Gold	2300-2500	0.35
Medikote™ C11	DLC	Black	2000-3000	0.1
Medikote™ C12	Me-DLC	Black	1000-2000	0.1
Medikote™MI-8	AlTiCN	Black	1200-1800	0.2

Data generated from lab samples. Characteristics may vary depending on customer's material, surface condition and part geometry.

All of our Medikote™ PVD coating processes are validated using flat stainless steel coupons. As PVD is a line-of-sight coating process and, thus, geometry dependent, a part specific validation or a correlation study may be required for your parts. The costs for a part specific validation or correlation study are not included in standard pricing.

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