



# SilcoTek®

Game-Changing Coatings™  
for the Medical Industry

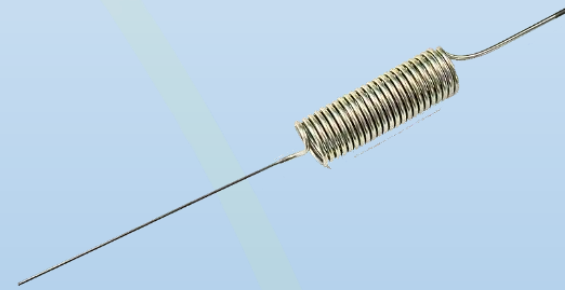


# Presentation Contents:

- An Overview of SilcoTek Corporation
- SilcoTek's CVD Coating Process
- SilcoTek's Coating Solutions for the Medical Industry
- Applications of SilcoTek's Coating Solutions in the Medical Industry
- Biocompatibility Testing, Certifications and Compliance of SilcoTek's Coatings
- Options to Evaluate SilcoTek Coated Parts at Your Facility
- Resource Information about SilcoTek's Coatings
- Questions



# SilcoTek's Coating Solutions for the Medical Industry



# An Overview of SilcoTek

- Year Founded: 2009
- Number of Employees: 60
- Our Mission: To create game-changing coatings
- Our Business: Chemical Vapor Deposition (CVD) coating services



# An Overview of SilcoTek

## Our History:

### ➤ 1987

Restek invents Silcosteel to coat SS tubing for the chromatography industry

### ➤ 1990-2000

A team is formed at Restek to investigate new coatings for other applications and markets

### ➤ 2000 - 2008

Launch and growth of Restek Performance Coatings Division

### ➤ 2009

Restek Performance Coating Division spins off to form SilcoTek

### ➤ 2013

SilcoTek builds 36,000 ft<sup>2</sup> state-of-the-art coating facility

### ➤ 2019

32,520 ft<sup>2</sup> addition to the original facility is completed adding additional coating capacity and office space



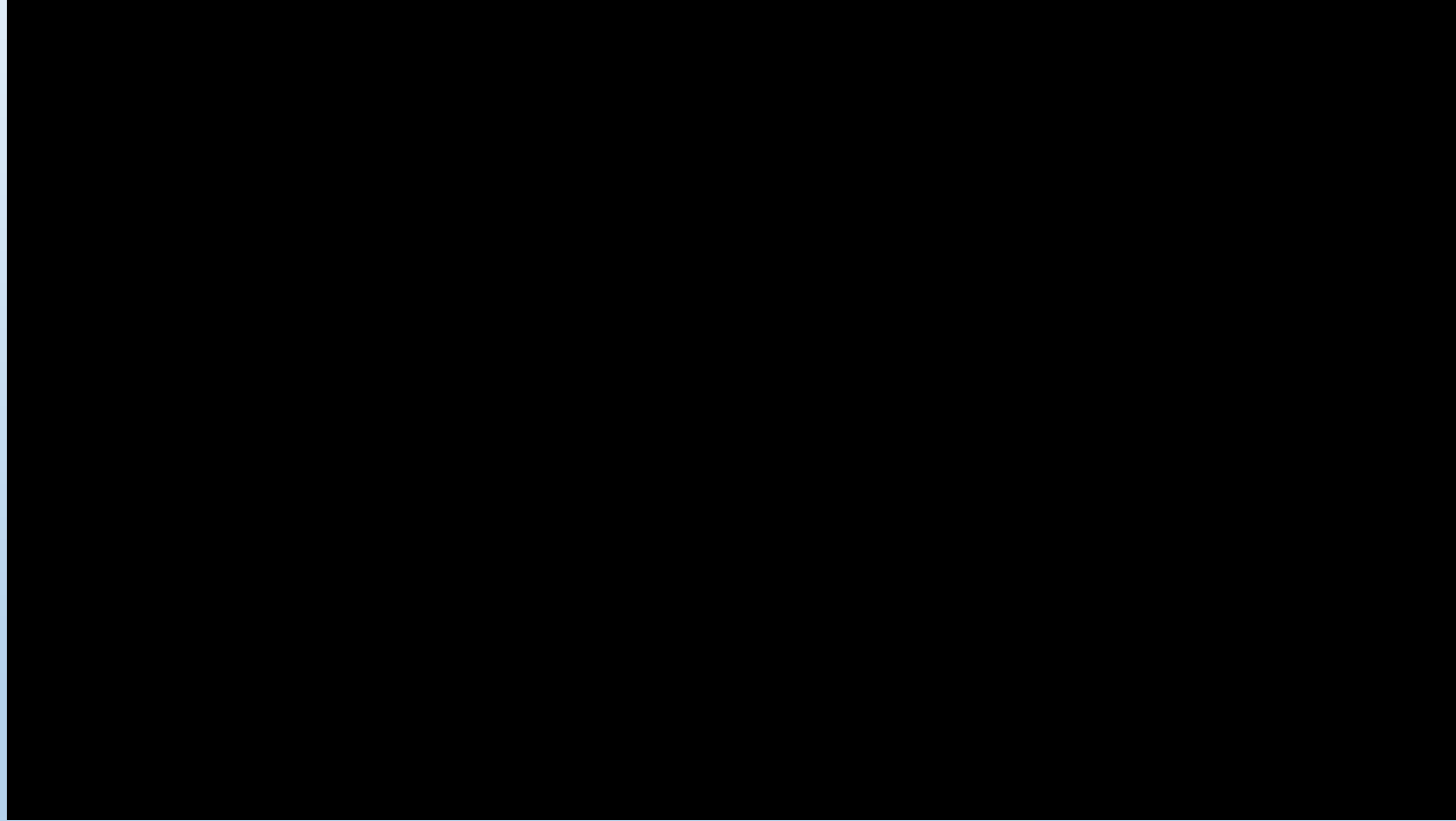
# An Overview of SilcoTek

## Our Markets:

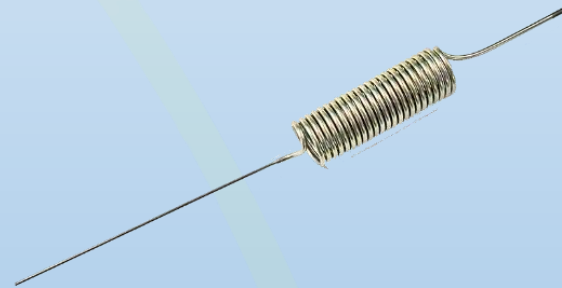
- Medical (Pharmaceutical, Clinical Diagnostics and Devices)
- Plastic Molding
- Packaging
- Plastic Molding
- Oil and Gas Exploration and Production
- Refining
- Gas and Liquid Chromatography
- Semiconductor Manufacturing
- Process Analytical
- Chemical Manufacturing
- Aerospace
- Automotive



# SilcoTek's CVD Coating Process



# SilcoTek's Coating Solutions for the Medical Industry





# What Problems in Medical Applications can be Solved Using SilcoTek's Coating Technology?

## Problem #1:

- Protein sticking to components such as transfer sample needles creating testing inaccuracies

## Problem #2:

- Corrosion of metal surfaces from harsh chemicals such as bleach as well as Disinfection and Sterilization liquids

## Problem #3:

- Metal ion leaching from metal equipment parts creating testing inaccuracies

## Problem #4:

- Buildup of blood, protein and other bio-media onto metal or glass surfaces



# What Solution Can SilcoTek's Coating Technology Provide to Solve These Problems?

## Dursan!

- SilcoTek's Dursan is an amorphous silicon oxide ( $\alpha\text{-SiO}_x\text{CH}_y$ ) coating applied via our proprietary CVD (Chemical Vapor Deposition) process
- It can be applied to metal substrates, such as stainless steel, carbon and tool steel alloys as well as aluminum
- Application specifications include:
  - operating temperature range of  $450^\circ\text{C}$  to  $-210^\circ\text{C}$
  - thickness of 400 – 1600nm
  - contact angle of  $\geq 81^\circ$
  - allowable pH of 0 - 14



# What are the Performance Benefits of using Dursan® in my Medical Component Applications?

- **Reduces protein carryover...**

Dursan's low surface energy prevents protein and other bio-media from sticking reducing carryover, improving test accuracy and device cleaning

- **Improves corrosion resistance...**

Dursan protects metals from harsh cleaning, disinfection and sterilization chemicals prolonging medical component and device lifetime

- **Prevents contamination...**

Metal ion leaching from components is avoided with Dursan's bio-inert barrier in the flow path

- **Excellent adhesion properties...**

Dursan is chemically bonded and molecularly fused onto to your component's surface to prevent flaking

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- **Safe to Use...**

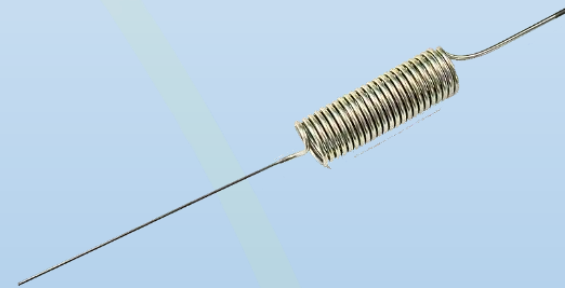


Dursan has passed USP Class VI Plastics testing and is certified by NSF International

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# Applications of SilcoTek's Coating Solutions in the Medical Industry



# What are Typical Applications in the Medical Market that Dursan<sup>®</sup> Be Used In?

- Transfer sample needles
- Trocars
- Surgical needles
- Well blocks
- Syringes
- Surgical tools
- Centrifuges
- Guide Wires
- Ampoules



# Biocompatibility Testing

**Dursan**® has passed the following Biocompatibility Tests:

- **USP Biological Reactivity Tests, *In Vivo* / USP Plastic Class VI**
- **Cytotoxicity Study Using the ISO Elution Method**

All of the above tests were completed by **NAMSA**, a very reputable test laboratory, which was the first independent company in the world to focus solely on testing medical device materials for safety.

**NAMSA**®



# Certifications & Compliance Statements

- **SilcoTek® is ISO 9001:2015 certified by the independent auditing firm BSI America Inc.**

Registration to ISO 9001 demonstrates SilcoTek's commitment to Zero Customer Disappointments, continuous quality system improvement and customer service.



- **NSF (National Sanitation Foundation) Certification**

Our [Dursan®](#) coating is compliant with NSF/ANSI 51 and all applicable requirements. This means that it is safe for food contact and also meets the FDA's requirements for compliance.



- **California Proposition 65**

SilcoTek® coatings do not contain chemicals which are listed on the state of California Safe Drinking Water and Toxic Enforcement Act of 1986, California Proposition 65. Proposition 65 protects California drinking water from contamination by chemicals known to cause cancer, birth defects, and other reproductive harm.



# Certifications & Compliance Statements

- **RoHS 3: Restriction of Hazardous Substances Directive 2015/863/EU**

SilcoTek® coatings do not contain any compounds at levels exceeding RoHS compliance limits such as Cadmium, Mercury, Lead, etc.



- **REACH-SVCH: Registration, Evaluation, Authorization, and Restriction of Chemicals - Substances of Very High Concern**

SilcoTek coatings do not contain any of the 201 REACH Substances of Very High Concern (SVHC) as updated by the European Chemicals Agency (ECHA)



- **Safety Data Sheet (SDS) Exemption**

SilcoTek® does not provide SDSs for our coatings as they are not hazardous chemical products.



# What are my Options to Evaluate Dursan in my Packaging Applications?

There are (2) options:

- Ship your packaging components to SilcoTek to be coated to evaluate the performance benefits of Dursan in your production line.
- Request Dursan coated test coupons to be shipped to your facility to be evaluated in a laboratory scaled environment.



# Need Additional Information about SilcoTek and our Coatings?

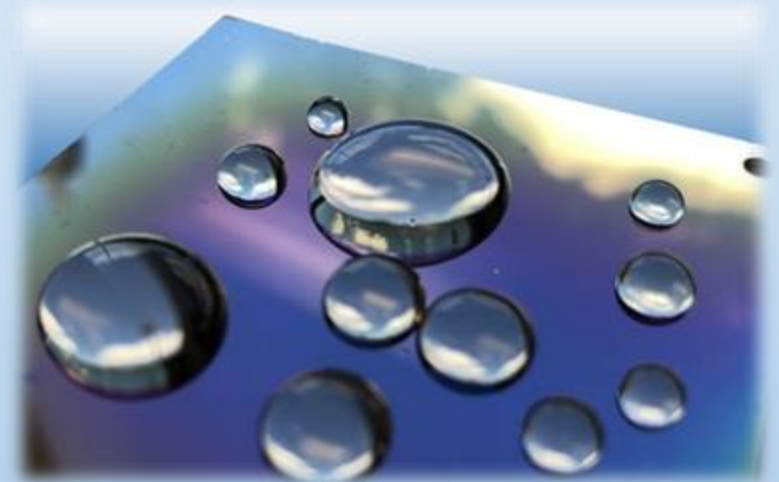
**Be sure to visit SilcoTek's website for additional resource information such as:**

➤ Literature:

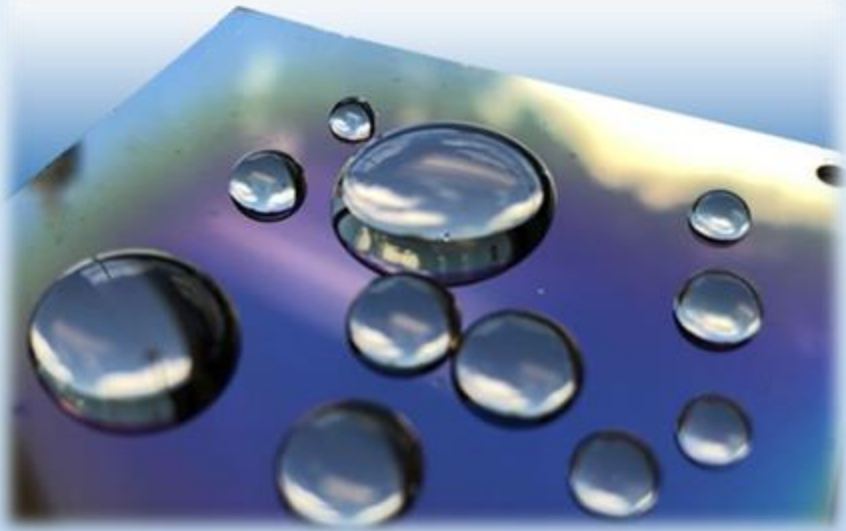
- “CVD Coatings for Medical Devices” Application Brief
- SilcoTek 101 Brochure
- Dursan Coating Data Sheet
- Coating Material Compatibility Guide
- Coating Chemical Compatibility Chart
- Coating Application Guide
- Coating Case Studies

➤ Services

- Get Technical Support
- Receive no-charge “evaluation coupons” for initial testing
- Request a Quotation



# Questions?



# Thank You for Your Time to Review Our Presentation!

