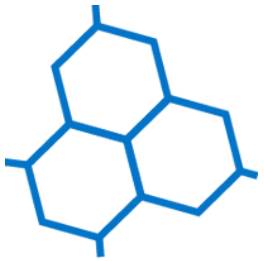
Alternative sterilization techniques to EtO for Delrin® polyoxymethylene

Liz Stubbs, Ned LeMaster

NA MGMC 2025

Patient-centric approach to medical device development



Materials & chemistries

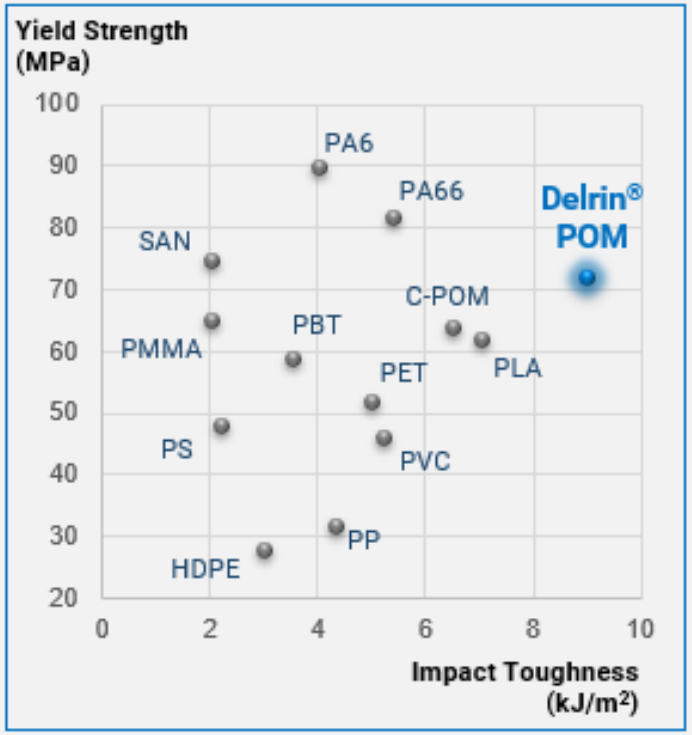
Patient safety & well-being

Sterilization & sanitation processes

Delrin®

Delrin®: Long-term commitment to the medical industry

Delrin® POM: Unique product



Dedicated grades for key healthcare applications

Added regulatory support & extended change notification

Flow Family	"100" MFR 2.3	"500" MFR 15	"900" MFR 25
Characteristics	**High Viscosity**	**Medium Viscosity**	**Low Viscosity**
Unmodified Grades	SC631	SC655	SC690, PC690
Low Friction	SC637	PC652	SC698

All grades can be available as Renewable Attributed versions with up to 75% reduction in CO_2 footprint.

The essential component in medical devices

- Surgical instruments
- Device casings
- Clips, clamps & connectors
- Vial trays & containers

Delrin®

Increasing scrutiny surrounding sterilization modalities

Ethylene oxide and gamma radiation are widely utilized

+ Effective sterilization
+ Excellent material compatibility
+ Ability to implement on large scales

Increasing scrutiny and concern

EPA announces final rule to slash toxic emissions of ethylene oxide and reduce cancer risk

March 14, 2024

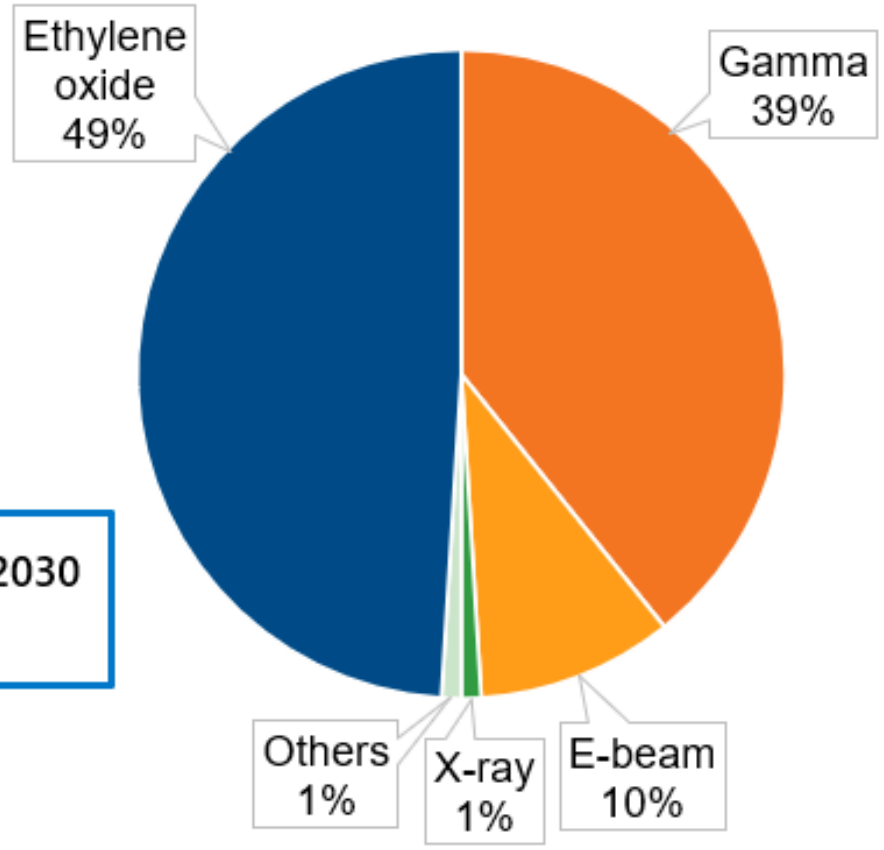
ENVIRONMENTAL Science & Technology

ARTICLE | February 19, 2020

Perspective on Cobalt Supply through 2030 in the Face of Changing Demand

Further innovation and use of all modalities contribute to sterilization reliability in the medical space.

Sterilization modality use breakdown[1]



[1]National Academies of Sciences, Engineering, and Medicine. *Radioactive Sources: Applications and Alternative Technologies*. 2021.

Delrin®

State-of-the art sterilization techniques

				"Others"		
Sterilization modality / Parameter	Radiation (gamma, e-beam)	Ethylene oxide (EO)	Autoclave	Vaporized hydrogen peroxide (VHP)	Chlorine dioxide (CD)	Nitrogen dioxide (NO_2)
Carcinogenic	No	Yes	No	No	No	No
Temperature	30 – 60 °C	37 – 63 °C	120 – 130 °C	28 – 60 °C	10 – 30 °C	15 – 30 °C
Humidity	Dry	≥ 40 %RH	≥ 40 %RH	≥ 50 %RH	≥ 40 %RH	≥ 40 %RH
Process length	hours to days	hours to days	3 – 30 min	2 – 10 h	3 – 8 h	6 – 8 h
Aeration time	No	12 – 96 h	No	1 – 4 h	30 min	30 min – 2 h
Compatible with cellulosic packaging?	Yes	Yes	No	No	Yes	No
Delrin compatible?*	Not recommended	Compatible*	Compatible*	Compatible*	Compatible*	Not recommended

* Compatible with most Delrin grades under typical use conditions. It is best to consult a Delrin representative to discuss sterilization compatibility in the specific-use case.

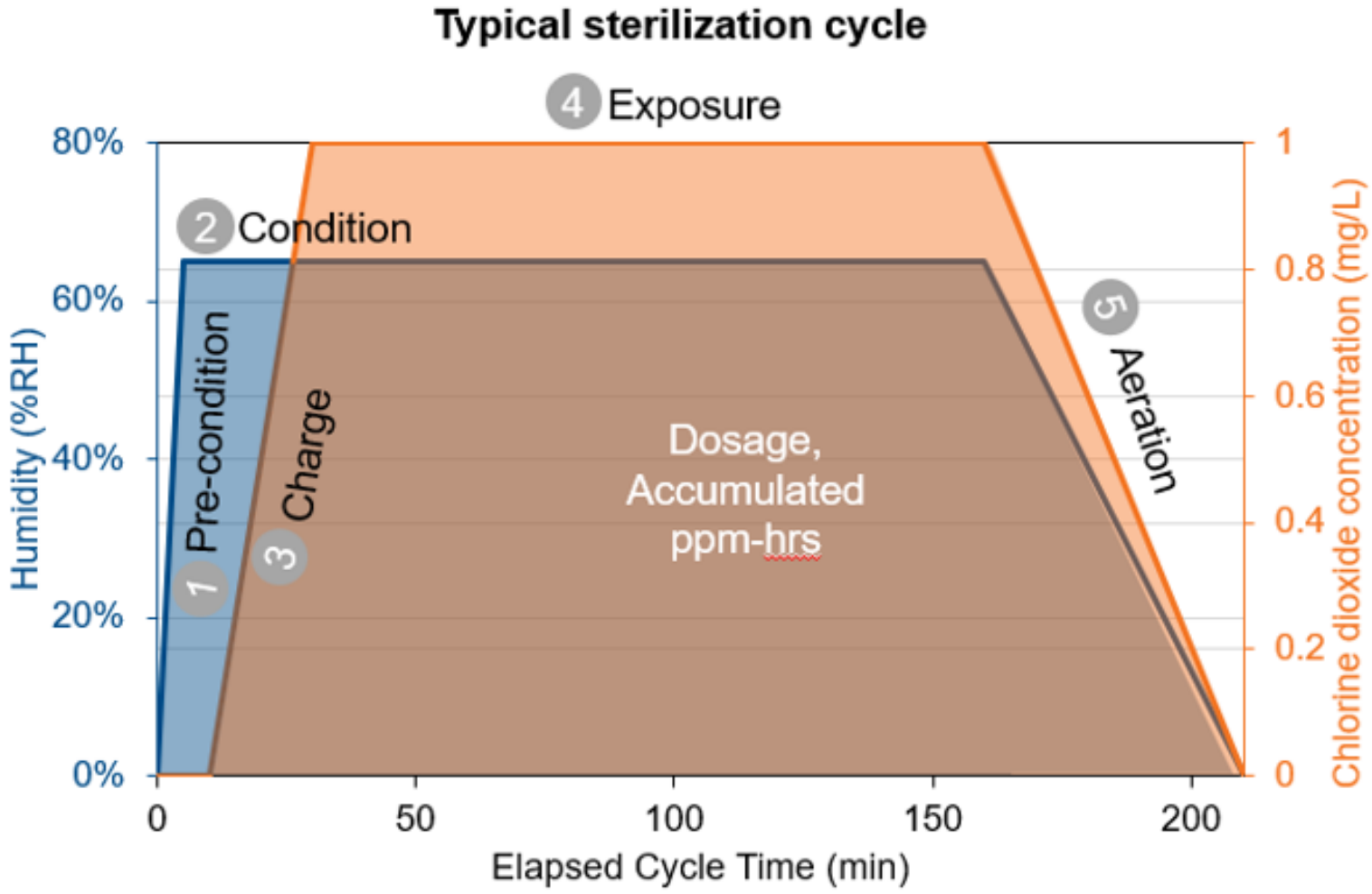
Various experts in the field and O'Dell, G.; Hodge, S. AAMI News. *Alternative Sterilization Modalities to EtO: Let's Compare & Contrast*. July 2024.

Delrin®

CD sterilization: Broad use & process customization

Applicable across a broad set of healthcare applications

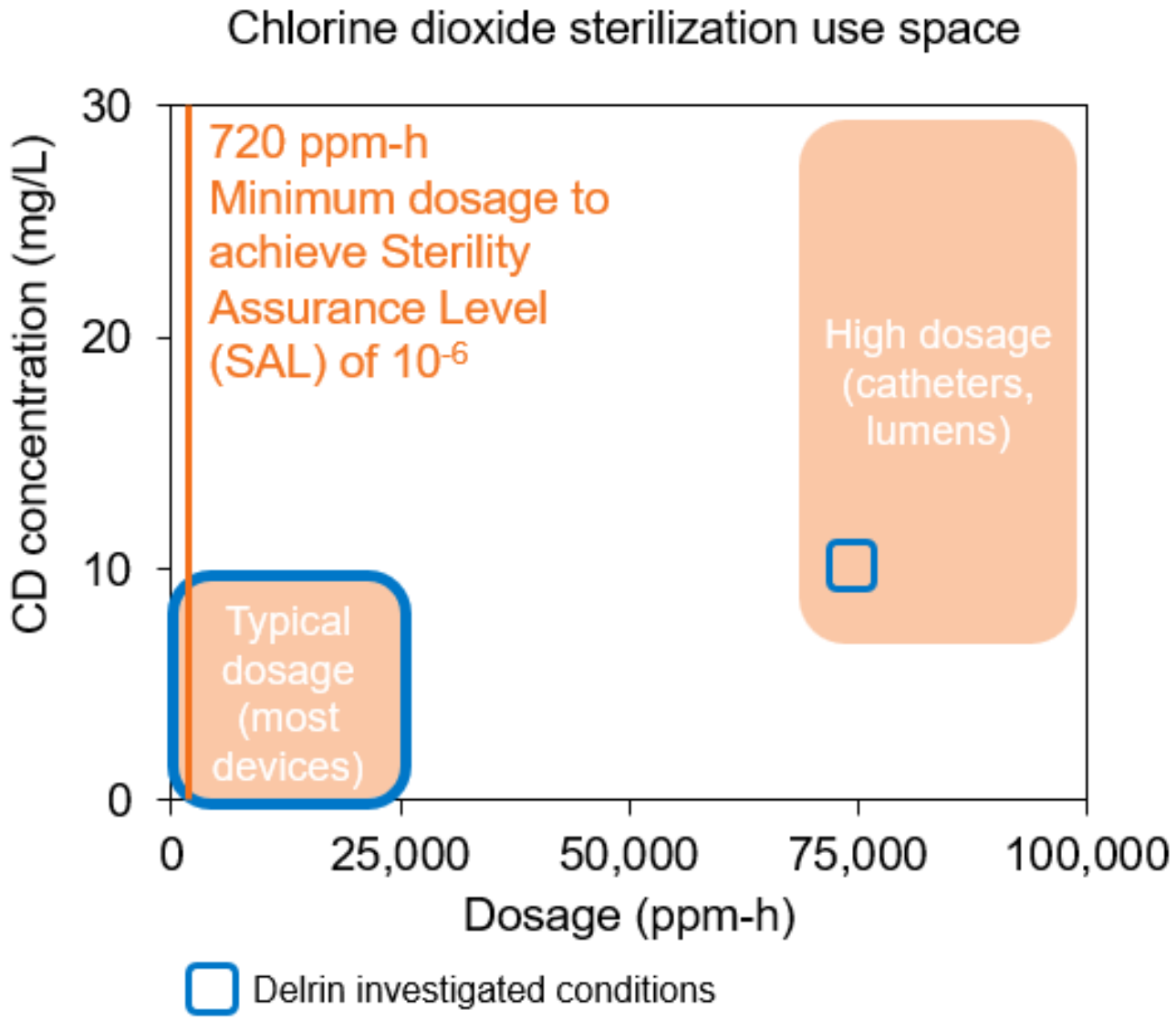
- Tubing and catheter sets
- Surgical devices
- Electronic devices
- Empty and pre-filled syringes



Adapted from clordisys.com

Delrin®

Typical CD sterilization conditions

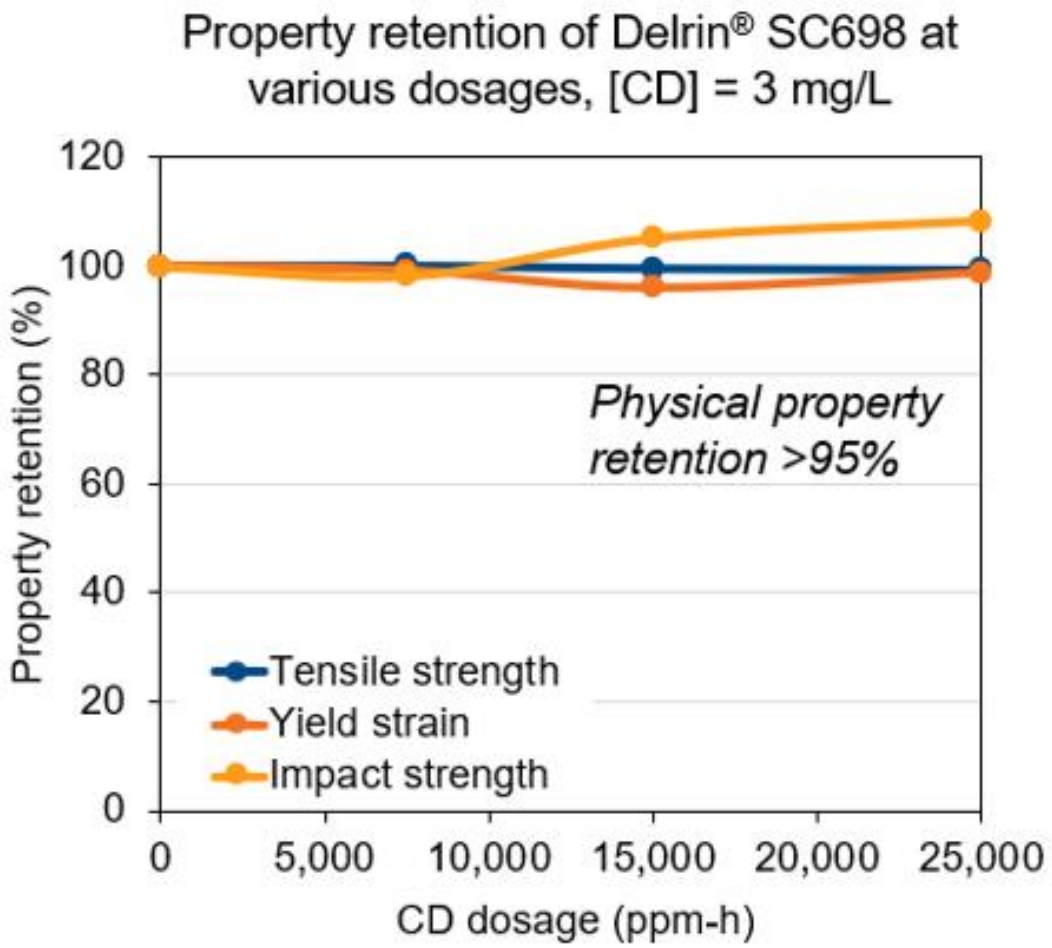


Delrin® tensile bars sealed in Tyvek® bags to undergo CD sterilization

ClorDiSys

Delrin®

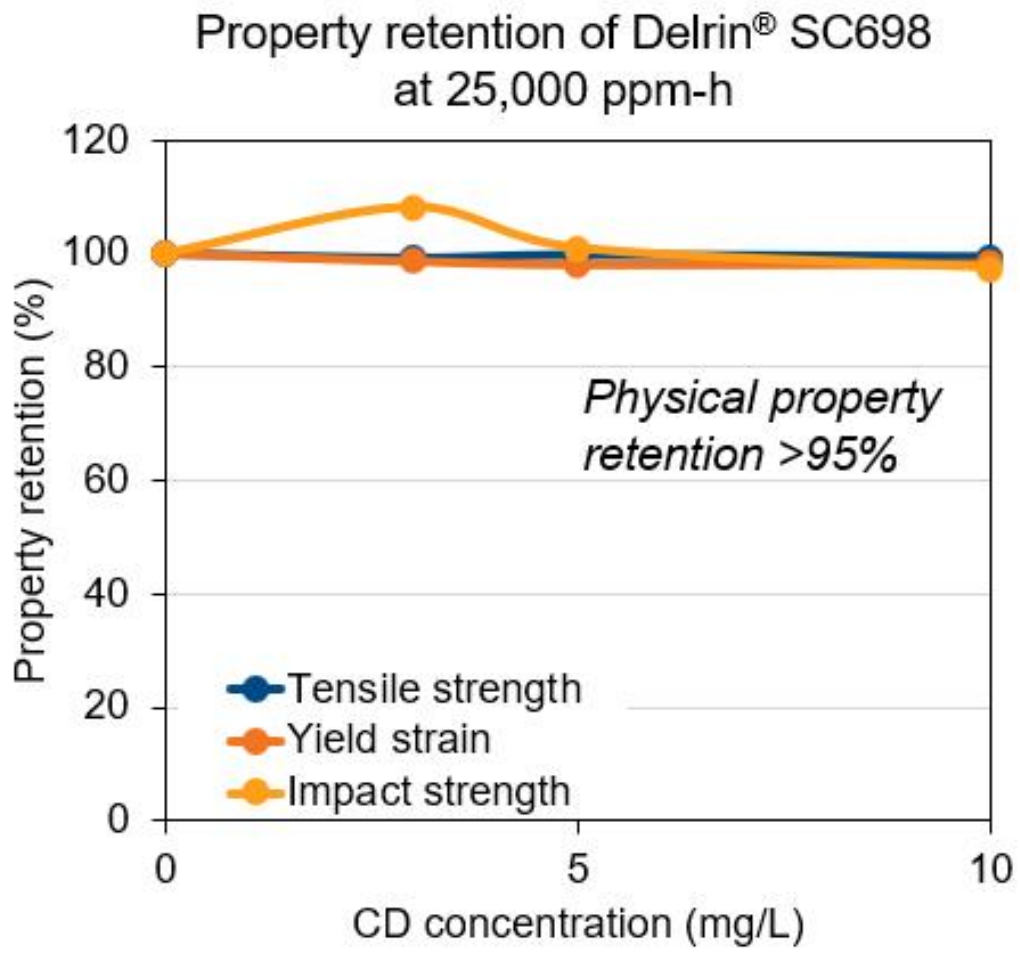
Delrin® retains physical properties under typical CD exposure conditions



Delrin® SC698 retains mechanical properties and has minimal color change after typical CD exposure

Increasing CD dosage

Achieve higher dosage in shorter times without impacting physical properties



Increasing concentration, reduces exposure time at 25,000 ppm-h while maintaining physical properties

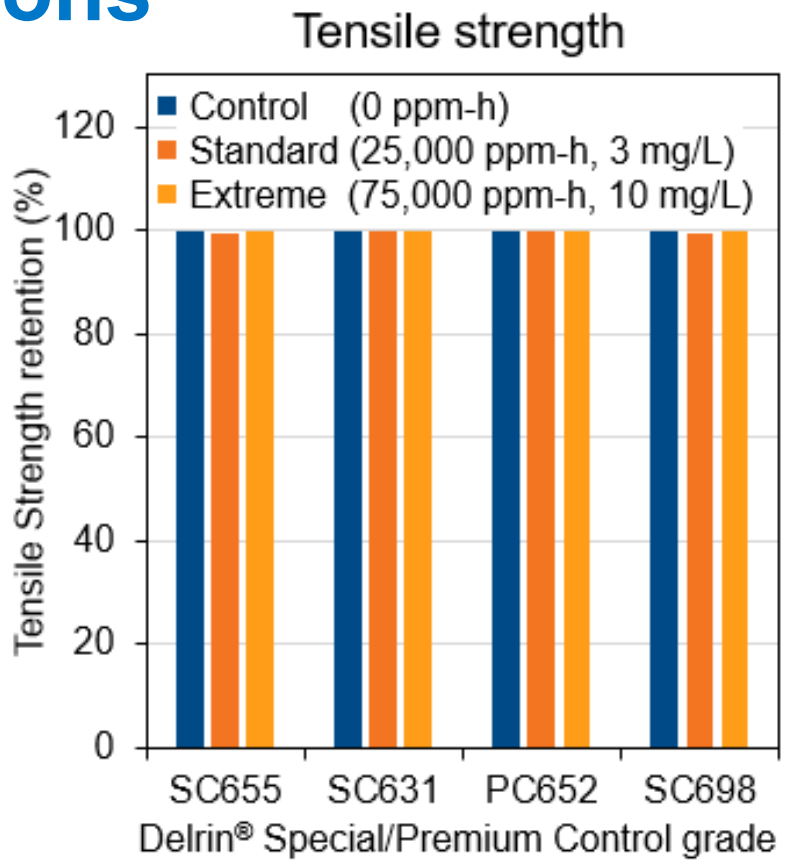
Increasing [CD] at 25,000 ppm-h

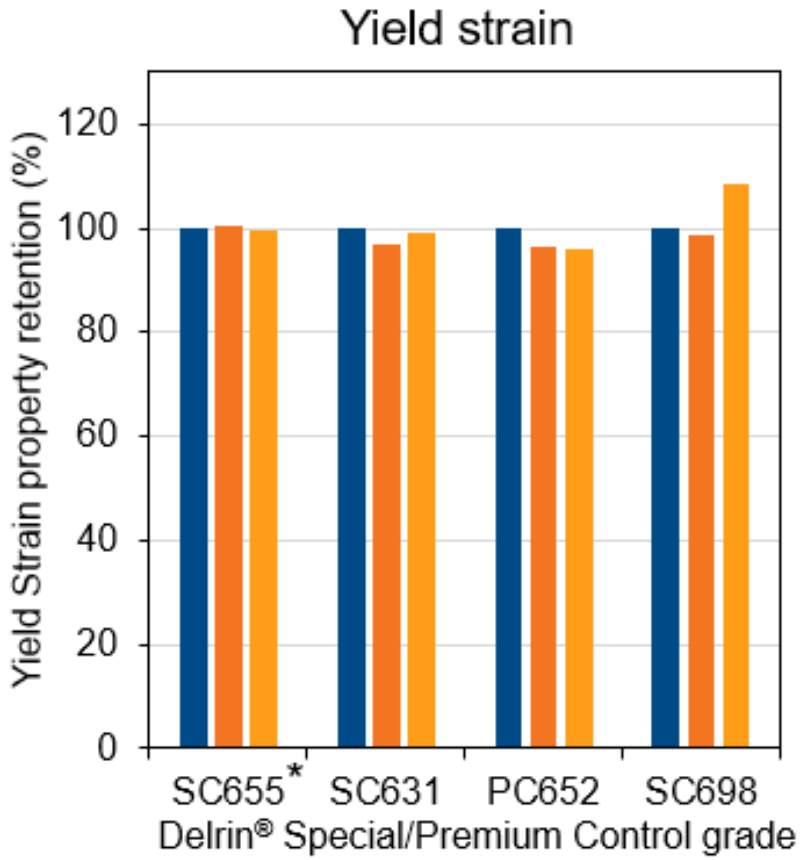
Exposure time to achieve 25,000 ppm-h

[CD] (mg/L)	Time (h)
3	23
5	14
10	7

Delrin®

Delrin® compatibility with CD sterilization under extreme conditions





Several Special/Premium Control Delrin® grades show high property retention after extreme (high dosage, high concentration) CD sterilization

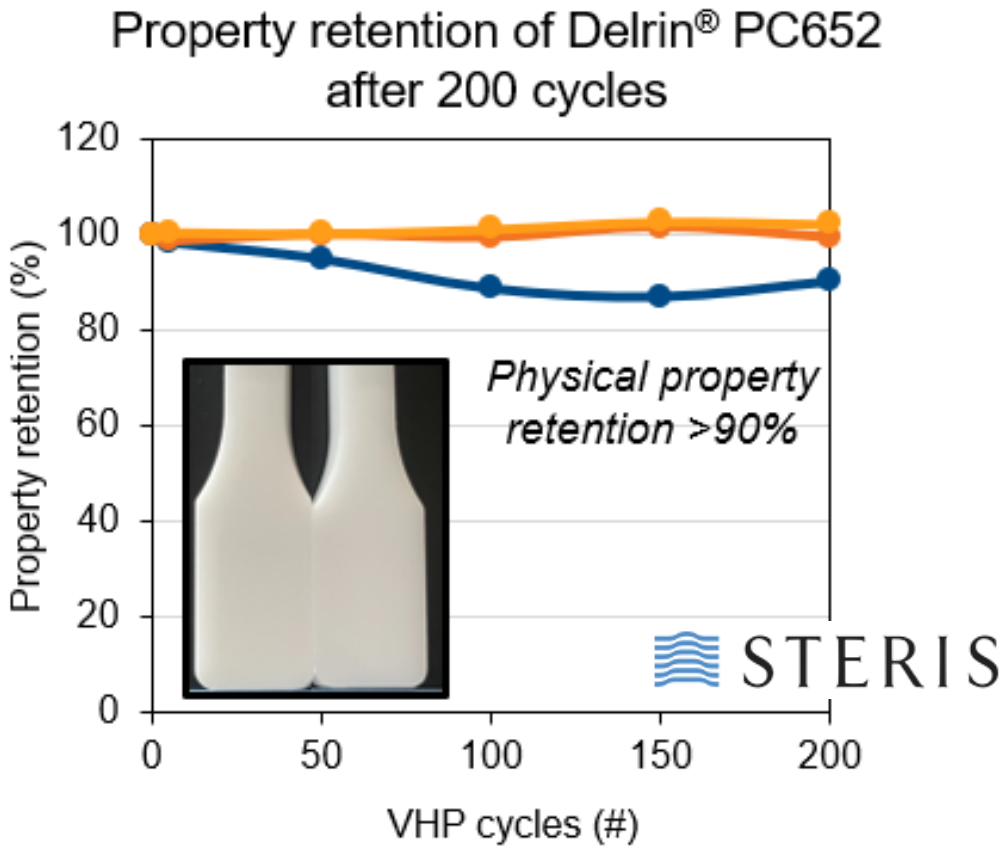
*Nominal strain at break reported

Delrin®

Delrin® compatibility with VHP sterilization under extreme conditions

More oxidizing potential ↓

Sterilant	Oxidation Potential
Chlorine dioxide	0.96
Nitrogen dioxide	0.99
Hydrogen peroxide	1.78
Peracetic acid	1.81



Several Special/Premium Control Delrin® grades show good mechanical property retention with VHP sterilization

Delrin®

Delrin® as a safe, reliable, sustainable solution

CD and VHP are effective sterilants

Chlorine dioxide and vaporized hydrogen peroxide are effective and broadly compatible sterilization techniques

Delrin has sterilization compatibility

Delrin® has broad sterilization compatibility with chlorine dioxide, vaporized hydrogen peroxide, and ethylene oxide

Full portfolio of Healthcare solutions

Healthcare solutions with regulatory support & extended change notifications

Design partner of choice

Formulation, design, processing, application & regulatory expertise dedicated to customer success

Delrin®

Delrin® – Long-term Commitment to the Healthcare Industry

ClorDiSys
Emily Lorcheim

STERIS
Alison Barrett, Randy Eveland

NORTH AMERICA MGMC MEDICAL MATERIALS

J&J MedTech | R&D Materials OneMDSpecEngineering

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