Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing

Cecilia Pierobon, Manager, Technical Services

Cecilia_Pierobon@STERIS.com

©2026 STERIS. All rights reserved.

STERIS

Agenda

- Introduction to Silicone Oil and Closure Siliconization
- Understanding the Risks of Silicone Oil Residues
- Cleaning Assessment Strategies
- Establishing Acceptable Residue Limits

©2026 STERIS. All rights reserved.

STERIS

Cleaning Process Design for Filling Line Equipment

Product contact parts

Final product formulation → Final product formulation tank

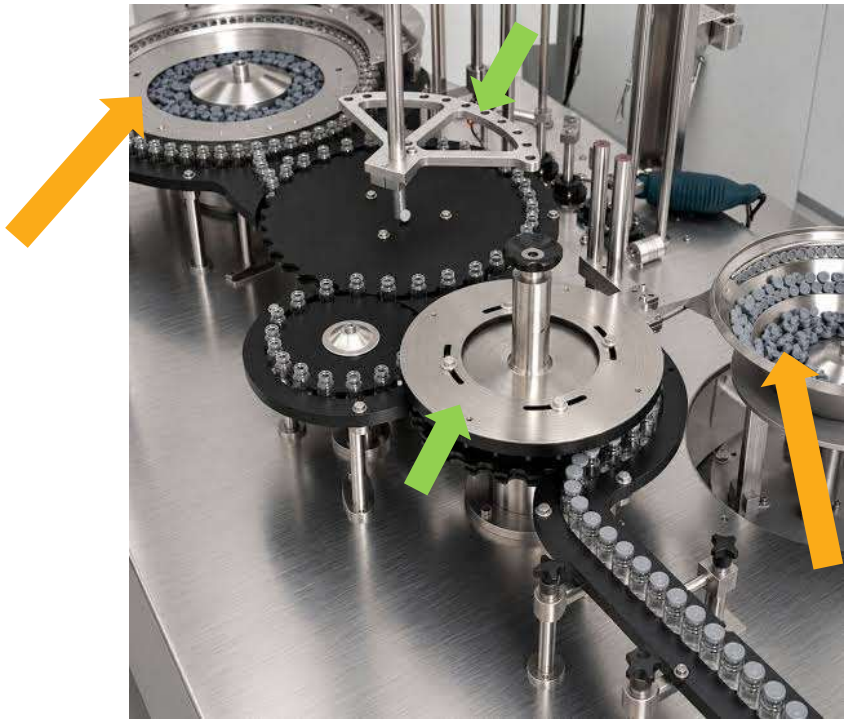
↓ Sterile filter

↓ Filling pump and hoses

↓ Filling needles

↓

Non product contact parts



Indirect contact parts

©2026 STERIS. All rights reserved.

STERIS

Siliconization of Closures

- Silicone oil is a lubricant. The primary functions of the lubricant are (PDA, TR12):
  - smooth transfer of the closure (stoppers, plunges),
  - smooth processing on the filling line (machinability),
  - correct stopper insertion into product vial or introduction of the plungers into the syringes,
  - ensure integrity of the seal between the closure and primary packaging.



Image source: https://www.bd.com/en-us/products-and-solutions/products/product-families/scf-premiumcoat-plunger-stopper



From standardized products to co-engineering

With our products, we not only ensure that our components meet the highest standards, but also that they cover a wide range of potential, individual needs. We support our customers in finding or developing the right packaging solution for their product.

Image source: https://datwyler.com/healthcare/applications/vials/

©2026 STERIS. All rights reserved.

STERIS

Cleaning Requirements according to the Type of Surface

Level of risk



Direct Product Contact

Visual inspection
Cleaning Validation
- MACO/PDE
- Analytical methods
- Sampling methods





Indirect Product Contact

Visual inspection only?
Cleaning Validation?
- MACO/PDE?
- Analytical methods?
- Sampling methods?





Non-Product Contact

Visual inspection only

©2026 STERIS. All rights reserved.

STERIS

Issues with Silicone Oil Residues

- Visually clean criteria not being met.
  - EU Annex 1, Annex 15, FDA Guidance on Cleaning

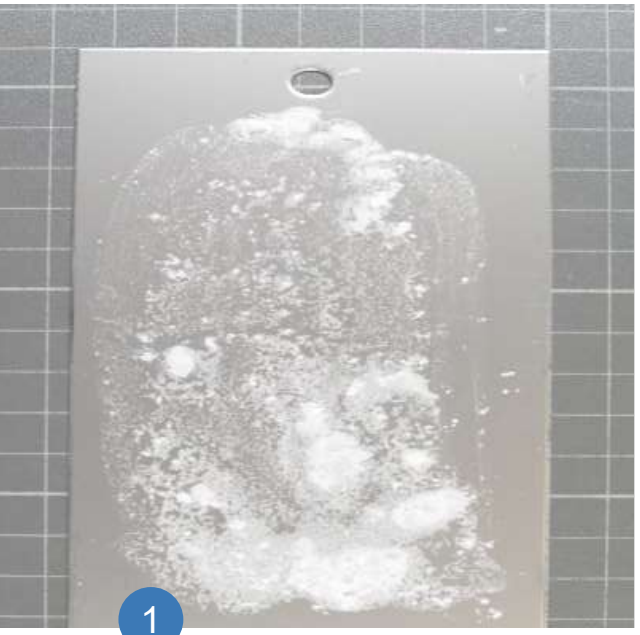
- Higher risk of particles and microbial contamination due to sticky surfaces.
  - EU Annex 1

Ref: Riley S., Pierobon C., Hadziselimovic D., Lopolito P. ,“Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing”, Pharmaceutical Technology, September 10, 2026

©2026 STERIS. All rights reserved.

STERIS

PACE® Program Process and Cleaner Evaluation



1

SS coupons are spiked with sample soil(s)



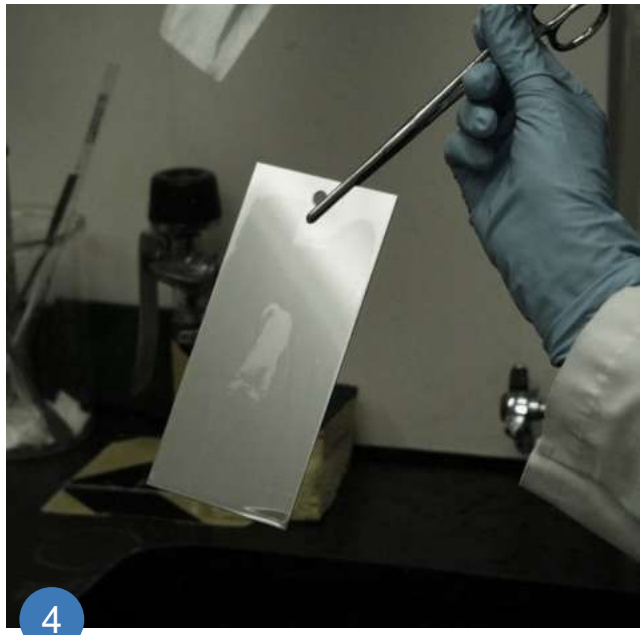
2

Soil conditions are emulated to the actual manufacturing process



3

Coupons exposed to multiple cleaning parameters depending upon project objectives



4

Visually clean? Water break free? Weight change? Analytical tests?

©2026 STERIS. All rights reserved.

STERIS

Effect of cleaning agent, concentration, time, and temperature

AI: agitated immersion; SW: spray wash; CF: cascading flow

Cleaning agent	Dirty hold time (hrs)	Concentration	Temperature (°C)	Cleaning time (min) Required per Method		
				AI	SW	CF
Formulated alkaline KOH detergent	24	1% v/v	60	15	5	15
	96	1% v/v	60	10	5	15
			80	5	N/A	N/A
Formulated alkaline NaOH detergent	24	1% v/v	60	15	5	30
	96	1% v/v	60	10	5	15
			80	5	N/A	N/A
Formulated neutral detergent	24	1% v/v	60	10	N/A	N/A
	96	1% v/v	60	F	F	F
			80	45	N/A	N/A
		3% v/v	60	15	N/A	N/A
NaOH	24	0.5 M	80	F	F	F
DI water	24	N/A	80	F	F	F

©2026 STERIS. All rights reserved.

Ref: Riley S., Pierobon C., Hadziselimovic D., Lopolito P. ,"Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing", Pharmaceutical Technology, September 10, 2026

STERIS

Effect of cleaning agent, concentration, time, and temperature

AI: agitated immersion; SW: spray wash; CF: cascading flow

Cleaning agent	Dirty hold time (hrs)	Concentration	Temperature (°C)	Cleaning time (min) Required per Method		
				AI	SW	CF
Formulated alkaline KOH detergent	24	1% v/v	60	15	5	15
	96	1% v/v	60	10	5	15
			80	5	N/A	N/A
Formulated alkaline NaOH detergent	24	1% v/v	60	15	5	30
	96	1% v/v	60	10	5	15
			80	5	N/A	N/A
Formulated neutral detergent	24	1% v/v	60	10	N/A	N/A
	96	1% v/v	60	F	F	F
			80	45	N/A	N/A
		3% v/v	60	15	N/A	N/A
NaOH	24	0.5 M	80	F	F	F
DI water	24	N/A	80	F	F	F

©2026 STERIS. All rights reserved.

Ref: Riley S., Pierobon C., Hadziselimovic D., Lopolito P. ,"Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing", Pharmaceutical Technology, September 10, 2026

STERIS

Effect of cleaning agent, concentration, time, and temperature

AI: agitated immersion; SW: spray wash; CF: cascading flow

Cleaning agent	Dirty hold time (hrs)	Concentration	Temperature (°C)	Cleaning time (min) Required per Method		
				AI	SW	CF
Formulated alkaline KOH detergent	24	1% v/v	60	15	5	15
	96	1% v/v	60	10	5	15
			80	5	N/A	N/A
Formulated alkaline NaOH detergent	24	1% v/v	60	15	5	30
	96	1% v/v	60	10	5	15
			80	5	N/A	N/A
Formulated neutral detergent	24	1% v/v	60	10	N/A	N/A
	96	1% v/v	60	F	F	F
			80	45	N/A	N/A
		3% v/v	60	15	N/A	N/A
NaOH	24	0.5 M	80	F	F	F
DI water	24	N/A	80	F	F	F

©2026 STERIS. All rights reserved.

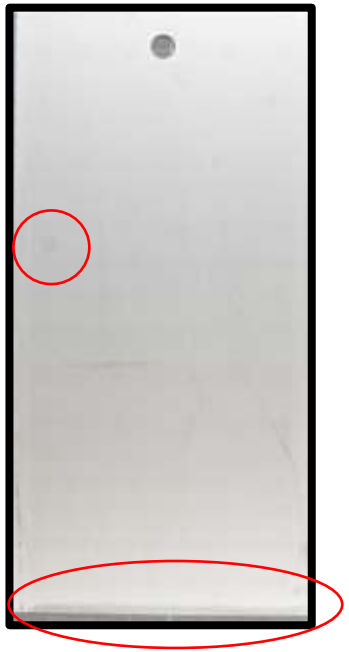
Ref: Riley S., Pierobon C., Hadziselimovic D., Lopolito P. ,“Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing”, Pharmaceutical Technology, September 10, 2026

STERIS

Effect of cleaning agent, concentration, time, and temperature



†Residue on Al 0.5M NaOH at 80°C



*Trace Residue on SW DI Water at 80°C

Cleaning agent	Dirty hold time (hrs)	Concentration	Temperature (°C)	Cleaning time (min) Required per Method		
				Al	SW	CF
NaOH	24	0.5 M	80	F†	F	F
DI water	24	N/A	80	F	F*	F

©2026 STERIS. All rights reserved.

Ref: Riley S., Pierobon C., Hadziselimovic D., Lopolito P. ,“Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing”, Pharmaceutical Technology, September 10, 2026

STERIS

Case Study: Cleaning Conditions for Dow Corning 360 Residue



- Representative stainless-steel coupons were soiled with the sample, air-dried at ambient temperature for 120 hours, and then cleaned by:
  - Agitated immersion
  - Spray Wash
  - Cascading Flow

Ref: Riley S., Pierobon C., Hadziselimovic D., Lopolito P. ,“Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing”, Pharmaceutical Technology, September 10, 2026

©2026 STERIS. All rights reserved.

STERIS

Case Study: Cleaning Conditions for Dow Corning 360 Residue



- Chemistry: Formulated, KOH-based alkaline detergent.

	Chemistry Concentration	Temperature	Time
Baseline condition	4% v/v	75°C	15 min
High-Pressure Spray (3 bar)	3% v/v	75°C	5 min
Hot water pre-rinse for 1 min	3% v/v	75°C	3 min

Ref: Riley S., Pierobon C., Hadziselimovic D., Lopolito P. ,“Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing”, Pharmaceutical Technology, September 10, 2026

©2026 STERIS. All rights reserved.

STERIS

Cleaning Requirements according to the Type of Surface

Level of risk



Direct Product Contact

Visual inspection
Cleaning Validation
- MACO/PDE
- Analytical methods
- Sampling methods





Indirect Product Contact

Visual inspection only?
Cleaning Validation?
- MACO/PDE?
- Analytical methods?
- Sampling methods?





Non-Product Contact

Visual inspection only

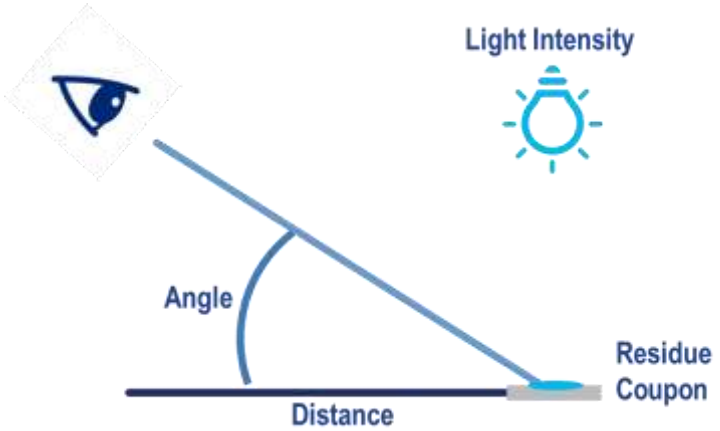
©2026 STERIS. All rights reserved.

STERIS

Confirming removal of silicone oil residues

- Traditional approach: using visual inspection only.

- New approach: calculating a limit using a PDE / ADE value and confirming it based on:
  - Visual Residue Limit (VRL),
  - Analytical method such as Fourier-transform infrared spectroscopy (FTIR).



Ref: Riley S., Pierobon C., Hadziselimovic D., Lopolito P. ,“Assessment of Silicone Oil Cleaning on Indirect Surfaces in Aseptic Manufacturing”, Pharmaceutical Technology, September 10, 2026

©2026 STERIS. All rights reserved.

STERIS

STERIS

Thank you for your attention!
Questions?

Come to visit us at our booth

Cecilia_Pierobon@STERIS.com, Technical Service Manager
Suda_Wipfli@STERIS.com, Account Manager Switzerland