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Autoclaving Guidelines for Opticap® XL and XLT Disposable Capsule Filters

Proper autoclaving is essential to maintaining capsule integrity over multiple sterilization cycles. Use the guidelines provided to ensure proper autoclave sterilization of Millipore Opticap XL and XLT disposable capsule filters.

The autoclave cycle conditions described are based on the maximum thermal and hydraulic stress resistance of the capsule and filter material.

Opticap XL and XLT Capsules

Opticap XL and XLT capsules are robust, reliable and easy to use. Their patented design allows for thermal and hydraulic stress resistance, minimizes hold-up and reduces production losses. Adjustable, easy-turn upstream vents and drain valves with o-ring seals and hose barb connections allow easy process control. Flow directional arrows and ribbed edges on the capsule cage make installation fast and simple. Proper autoclaving of each capsule will ensure capsule integrity over multiple sterilization cycles.

These recommendations are not intended as a substitute for validation. On-site filter sterilization validation must still be performed.

Guidelines

Autoclave Wet or Dry

Capsules may be autoclaved wet or dry. However process conditions should reflect the conditions present during on-site validation.

IMPORTANT: Do not, under any circumstances, in-situ steam sterilize Opticap XL or XLT capsule filter. Never use a deformed filter.

Vent Positions

The vents MUST remain open and unobstructed throughout the entire sterilization cycle to provide proper air displacement and condensate removal.

Inlet and Outlet Fittings

Inlet and Outlet openings must be unobstructed to allow maximum air displacement and steam flow, however the openings must be protected to prevent ingress of contamination post-sterilization. Devices can be sealed in autoclave pouches or the inlet and outlet fittings can be protected with sterilization wrap. Pouches or wrap must be chosen to ensure proper steam penetration and air displacement.

Failure to select the appropriate pouches or wraps can result in device damage or ineffective sterilization. If the wrap or pouch does not allow for unimpeded movement of air and steam during the autoclave cycle, it is possible to subject the device to excessive differential pressure. If the pressure is significantly higher in the chamber than the pressure in the capsule at (or near) the sterilization temperature, it is possible that the capsule could deform. This could occur during autoclave cycles with vacuum pulses during the come-up and/or the cool-down phase of the cycle. Ineffective sterilization due to wraps or pouches that impede steam or air flow is caused by the presence of air pockets or by the absence of sufficient moisture to effectively destroy microorganisms[1].
Never use a deformed capsule.

Tubing

Tubing with the largest possible inner diameter should be used. Tubing should not be crimped, or bent. If tubing is connected to both the inlet and outlet openings it should not be connected to form a continuous loop. Any tubing attached to the capsule MUST be open and unobstructed to provide adequate steam flow so that sterilization wrap can be placed on the ends for protection.

Clamps

Plastic clamps: Plastic two-piece sanitary clamps are recommended for autoclaving. These clamps are available with a torque stop to prevent over tightening.
Stainless steel clamps: Three-piece SS sanitary clamps are preferred over two-piece SS clamps for more uniform stress distribution.

IMPORTANT: Do not, over tighten clamps, over tightening can distort the fittings.

Fittings

Although the design of the capsule allows for multiple autoclave cycles, care must be taken when stainless steel parts are connected to the polypropylene capsule. The weight of these parts, coupled with the loss of the polypropylene's rigidity at autoclave temperatures, may result in capsule deformation. This issue is easily dealt with by supporting any stainless steel parts during the autoclave cycle.

Capsule Orientation

Capsules should be oriented as vertically as possible within the confines of the autoclave chamber. This will facilitate condensate drainage. When capsules are autoclaved in the horizontal direction, condensate collects and heat transfer is less efficient.

The position of the inlet and outlet of the capsule is important. For in-line Opticap XL capsules position the outlet fitting on the bottom (the flow arrow pointing downward). This will allow for maximum condensate drainage. For T-line Opticap XLT capsules the inlet and outlet fittings should be on the bottom. This will facilitate condensate drainage.

IMPORTANT: If hardware is attached to the capsule it must be supported. This is especially important if the capsule has a sanitary flange connection where additional components will generally be stainless steel. The clamps must be supported to prevent warping of the fitting during the autoclave cycle. Special attention should be given to the orientation of the vents so that they are not supporting the weight of the capsule during the autoclave cycle. This may cause distortion of the vents as the heat during the autoclave cycle softens the polypropylene.

Autoclaving

Capsules on a Process Tank

Autoclaving upright on a process tank is beneficial for two reasons. First, an aseptic connection to the sterile side is unnecessary and the sanitary capsule fitting is supported by the stainless steel tank fitting. Second it allows for the use of the three-piece SS clamp. The connection of additional hardware to the upstream side of the capsule is not recommended as it will not be supported and can result in capsule distortion.

Loose Capsules

The Opticap XL or XLT capsule may be placed loose in an autoclave for sterilization. Without any fittings attached, cover the openings with suitable sterilization wrap (as noted above) or place the entire capsule in an autoclave pouch. Then place into a basket or similar container. Make sure the capsule remains in a vertical position with the outlet at the bottom.

IMPORTANT: Loose Opticap XL capsules may inadvertently be placed upside down (inlet facing downward) if care is not taken during cycle loading. Please ensure that all capsules are oriented vertically with the flow arrow pointing downward. Improper loading will not impact the capsule integrity; however, the resulting increase in Fo value from condensate accumulation in the device core will impact sterility. Avoid placing the capsule in an upside down orientation during cycle loading.

Cycle Guidelines

Excessive differential pressures can result in damage to the capsule. This has been demonstrated by closing the high and low point bleeds and blocking the inlet and outlet connections in combination with autoclave cycles that utilize vacuum pulses during the come-up and cool-down portions of the cycle. Damage can be prevented by using the correct sterilization wrap or pouch. Selecting a slow exhaust (also known as liquid goods) cycle can also minimize the risk of damage. *See Thermal Stress Resistance Tables for detail.*

Troubleshooting

Loss of Capsule Roundness

An oval capsule body shape can be attributed to:

- Capping off the inlet and outlet connections as shown at right
- Accidentally joining the inlet and outlet tubing in a continuous loop
- Crimping inlet or outlet tubing connected to the capsule as shown at right
- Using autoclave paper that does not provide adequate steam flow
- Keeping vents closed during autoclaving

Fitting Distortion

Distortion or warping of capsule fittings can be attributed to their supporting excessive weight such as a heavy stainless steel clamp on a sanitary flange connection. Do not allow capsule fittings to support excessive weight. Also, overtightening clamps or using 2-piece stainless steel clamps can increase risk of deformation.

Vent Distortion

Vents may become distorted if the capsule weight is supported solely by the vents during an autoclave cycle. Capsules should NEVER be suspended solely by a vent and placed into the autoclave.

Never use a deformed capsule.

Thermal Stress Resistance

The autoclave cycle conditions described are based on the maximum thermal and hydraulic stress resistance of the capsule and filter material. These recommendations are not intended as a substitute for validation of filter autoclave sterilization cycles. On-site filter sterilization validation must still be performed.

Thermal Stress Resistance

Opticap XL with Durapore® Multimedia Membrane

Capsule Description	Pore Size	Catalogue No.	Time (Min.)	Temp (°C)	No. Cycles
Multimedia Opticap XL Capsule TC/TC 1pk	0.5+0.2+0.22 µm	KVSSA	60	123	3

Opticap XL with Lifegard™ Membrane

Capsule Description	Pore Size	Catalogue No.	Time (Min.)	Temp (°C)	No. Cycles
Opticap XL Capsule	1.0 µm	KP15A	60	121	3
Opticap XL Capsule	2.0 µm	KP20A	60	121	3

Opticap XL with Polysep™ II Membrane

Capsule Description	Pore Size	Catalogue No.	Time (Min.)	Temp (°C)	No. Cycles
Opticap XL Capsule	1.0+0.2 µm	KGW3A	30	121	3
Opticap XL Capsule	1.0+0.5 µm	KGW6A	30	121	3
Opticap XL Capsule	1.0+1.2 µm	KGW2A	30	121	3
Opticap XL Capsule	2.0+1.2 µm	KGW9A	30	121	3

Opticap XL with Milligard® Membrane

Capsule Description	Pore Size	Catalogue No.	Time (Min.)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.5+0.2 µm	KWSSA	30	121	3
Opticap XL Capsule	1.2+0.5 µm	KWSCA	30	121	3
Opticap XL Capsule	0.2 µm	KW03A	30	121	3
Opticap XL Capsule	0.5 µm	KW06A	30	121	3
Opticap XL Capsule	1.2 µm	KW19A	30	121	3

Opticap XL with Polygard® CR Membrane

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.1 µm	KRK1A	30	126	3
Opticap XL Capsule	0.3 µm	KRK3A	30	126	3
Opticap XL Capsule	0.5 µm	KRA5A	30	126	3
Opticap XL Capsule	1.0 µm	KR01A	30	126	3
Opticap XL Capsule	3.0 µm	KR03A	30	126	3
Opticap XL Capsule	5.0 µm	KR05A	30	126	3
Opticap XL Capsule	10.0 µm	KR10A	30	126	3
Opticap XL Capsule	25.0 µm	KR25A	30	126	3
Opticap XL Capsule	50.0 µm	KR50A	30	126	3
Opticap XL Capsule	75.0 µm	KR75A	30	126	3
Opticap XL Capsule	100.0 µm	KR99A	30	126	3

Opticap XL with Aervent® Membrane

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.2 µm	KTGRA	30	135	30

Opticap XL with Milligard® LPB Membrane

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.5+0.2 µm	KWLSA	30	121	3
Opticap XL Capsule	1.2+0.5 µm	KWLCA	30	121	3
Opticap XL Capsule	0.2 µm	KWL3A	30	121	3
Opticap XL Capsule	0.5 µm	KWL6A	30	121	3
Opticap XL Capsule	1.2 µm	KWL9A	30	121	3

Thermal Stress Resistance (cont'd)

Opticap XL with Polygard® CN Membrane

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.3 µm	KN03A	30	126	3
Opticap XL Capsule	0.6 µm	KN06A	30	126	3
Opticap XL Capsule	1.2 µm	KN12A	30	126	3
Opticap XL Capsule	2.5 µm	KN25A	30	126	3
Opticap XL Capsule	5.0 µm	KN50A	30	126	3
Opticap XL Capsule	10.0 µm	KN1HA	30	126	3
Opticap XL Capsule	30.0 µm	KN3HA	30	126	3

Opticap XL with Durapore® Membrane

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.22 µm	KVGLA	60	126	3
Opticap XL Capsule	0.1 µm	KVVLA	60	126	3
Opticap XL Capsule	0.45 µm w/Prefilter	KVHLA	60	121	3
Opticap XL Capsule	0.45 µm	KPHLA	60	125	3

Opticap XL with Hydrophobic Durapore® Membrane

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.22 µm	KVGBA	30	126	20

Opticap XL with Millipore Express® SHF Membrane

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.2 µm	KGEPA	60	126	3

Opticap XL with Millipore Express® SHC Membrane

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.5+0.2 µm	KHGEA	60	126	3

Opticap XL with Millipore Express® SHR Membrane and Prefilter

Capsule Description	Pore Size	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	0.5+0.1	KHVEA	60	126	3

Opticap XL with Viresolve® NFR Membrane

Capsule Description	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsules	KZRVA	60	125	1

Opticap XL with Viresolve® NFP Membrane

Capsule Description	Catalogue No.	Time (min)	Temp (°C)	No. Cycles
Opticap XL Capsule	KVPVA	60	123	1

Following the guidelines presented in the technical note for autoclave sterilization of Opticap XL or XLT disposable capsule filters will ensure that capsule integrity is maintained over multiple sterilization cycles.

These recommendations are not intended as a substitute for validation of filter autoclave sterilization cycles. On-site filter sterilization validation must still be performed.

References

1. Voorspoels, J., Remon, J.P., and Vendebossche, G., "Validation of Filter Sterilization in Autoclaves." Proc. 1st World Meeting APGI/APV, Budapest (9-11 May 1995). Journal of Pharmaceutical Science and Technology "Technical Monograph No. 1" Draft 18 2006 Revision

Go Mobius

Opticap XL and XLT capsules are a Mobius flexible bioprocessing technology and part of a suite of products that together provide an integrated disposable solution to improve process efficiency in biopharmaceutical development and manufacturing. From disposable process containers, capsule filters and connectors, to validated, gamma-compatible turn-key assemblies, Mobius solutions provide faster turnaround time and reliable performance, right out of the box.

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flexible bioprocessing solutions

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