

Dear Customer,

August 12, 2016

Process indicators on rigid containers are commonly used in hospitals to indicate, via a color change, whether instrument sets have been exposed to a sterilization process. The indicators are printed with an ink that may contain lead, which provides a robust and stable color change.

Aesculap has investigated using indicator dot inks which are environmentally friendly, by minimizing the use of heavy metals. However, after much research and testing we don't feel that the ink dot technology is yet where it needs to be in order to meet Aesculap quality standards and deliver consistent results.

The following charts show all the filters, locks and indicator cards that may be used with the Aesculap SterilContainer System, including those with and without process indicators. Products that contain lead are broken into those with less than and those with greater than 5 parts per million (ppm), the EPA regulated level.

Aesculap Filters, Locks and Indicator Cards

Locks	Modalities					Indicator Lead Content ¹		
	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp	<5ppm	>5ppm	DNA ⁵
Blue / US900 w/o Indicator	X	X	X	X	X			X
Green / US905 Change ³ Yellow to Orange				X			X	
Orange / US906 Change ³ Blue to Brown	X	X	X				X	
Pink / US910⁴ Change ³ Magenta to Blue					X ⁴	X ⁶		
Yellow / US399 Change ³ Blue to Brown		X					X	

Cards	Modalities					Indicator Lead Content ¹		
	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp	<5ppm	>5ppm	DNA ⁵
MD334, MD335 w/ Indicator Change Blue					X	X ⁶		
MD346, MD876, US754, MD347 w/ Indicator ² Change Brown in Steam Change Orange in EtO	X	X	X	X		X		
US963 w/o Indicator	X	X	X	X	X			X
MD399, MD345 w/ Indicator Change Brown		X				X		

Filters	Modalities					Indicator Lead Content ¹		
	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp	<5ppm	>5ppm	DNA ⁵
Paper Filter w/ Indicator ² US751	X ²	X ²	X ²	X ²		X		
Paper Filter w/o Indicator US994, US999	X	X	X	X				X
Polypropylene Filter w/o Indicator MD344, MD355	X	X		X	X			X
Aluminium Lid PTFE Reusable Filter JK090, JK091	X	X						X
PrimeLine PTFE Reusable Filter JP050	X	X						X

Processing Supplies Options With Less Than 5ppm of Lead

The chart below shows how to switch to products with under 5ppm of lead for each sterilization modality.

	Steam		EtO		Low Temp
	Instead of (>5ppm)	Use (<5ppm)	Instead of (>5ppm)	Use (<5ppm)	Does Not Apply ⁵
Lock	US906, US399	US900	US905	US900	No Change All Products <5ppm
Cards	No Change All Products <5ppm		No Change All Products <5ppm		
Filter	No Change All Products <5ppm		No Change All Products <5ppm		

See Aesculap SterilContainer Instructions for Use (www.aesculapusa.com/IFU) for details on proper use and application of containers and processing supplies.

Sincerely,



Paul Blackwell
Associate Director, Quality Assurance/Quality Control



Troy Scroggins
Product Manager, Containers

1. The method used to test the product was "Toxicity Characteristic Leaching Procedure, method 1311, specified in 40 CFR 261."
2. Contains a dual indicator dot which changes from blue to brown in steam, and to orange in EtO.
3. After sterilization, the external indicator should change from the original indicator color to the recommended post sterilization indicator color. **The recommended post sterilization indicator color may not be evenly shaded but should be shades of the proper processed color to indicate exposure to sterilant.**
4. Locks must be stored in a controlled room temperature, away from alkaline chemicals, acids and sources of light.
5. DNA = Does not apply, no process indicator and/or no lead content.
6. No lead content