



April 14, 2009

Re: FDA clarifies Class 6 Chemical Indicators should not be used in place of Biological Indicators

Dear Valued Customer:

There has been much confusion about the role of chemical indicators, particularly the Class 6 emulating indicator, in steam sterilization monitoring practices. 3M recognizes this is an issue for our customers and has been following industry communications on this topic. The current hospital sterilization standards do not provide a recommended use for these products, there is no published scientific data suggesting use different from that of any other chemical indicator used as an internal pack monitor, and the FDA has stated publically that the type of indicators used and the loads they are used in, is the responsibility of the healthcare provider.

Recently, the enclosed communication between Nancy Chobin of Saint Barnabas Health Care System in New Jersey and Sheila A. Murphey, MD (the Branch Chief of the FDA's Infection Control Devices Branch in the Center for Devices and Radiologic Health Office of Device Evaluation) was posted on the CBSPD website at <http://www.sterileprocessing.org/info.htm#ci>. This communication addresses the FDA's position on Class 6 chemical indicators.

Based on the communication between Ms. Chobin and Dr. Murphey posted on the CBSPD website, the FDA views the Class 6 chemical indicator similar to other chemical indicators they have cleared and not as a replacement for a BI.

If you have further questions regarding the 510(k) clearance of a medical device, you can always contact the FDA directly at 1-800-638-2041 or DSMICA@CDRH.FDA.GOV.

Sincerely,

A handwritten signature in black ink, appearing to read 'Bryan A. Becker'.

Bryan A. Becker
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Source: CBSPD Website <http://www.sterileprocessing.org/info.htm#ci>.

Important CBSPD Announcements

-- Important News on Chemical Indicators --

April 11, 2009 - 6 pm Eastern

Due to the number of emails and telephone calls received from around the US about class 6 chemical indicators, a communication was made with the FDA to get clarification about these devices:

Dear Sheila

I sit on the AAMI Sterilization Committee with you and would greatly appreciate some information. I work for the Saint Barnabas Health Care System in NJ and some of our facilities are being asked to switch to Class VI indicators to release all loads (including implants). As you know, AAMI has not covered these indicators. I am of the position that since these indicators do not contain spores we should not use them for implants or for routine or qualification testing of sterilizers.

The company's literature states they can be used for all loads and I am being told the sales rep stated that the FDA cleared their product to be used in lieu of a BI. Any clarification would be greatly appreciated so I can prepare my rebuttal.

Thank you
Nancy Chobin, RN, CSPDM

On 4/10/09 at 9:16 AM Sheila Murphey responded:

Dear Nancy,

Thank you for your email. If the Steris sales representative stated that FDA cleared the Steris Verify SixCess Chemical Indicator to be used in place of a Biological Indicator, then he made an incorrect statement. FDA cleared this device as a "Chemical Indicator". Chemical Indicators are used in the load release decisions made for all sterilizer loads for which they are used. Chemical Indicators measure ONLY the physical parameters of the sterilization cycle. Any decision made based on the use of a Chemical Indicator to monitor a sterilization load would apply to all items in a load, since the CI does not distinguish among items in any load (neither does a Biological Indicator).

However, the JCAHO and CDC have been recommending for many years that the microbicidal performance of a sterilizer cycle used to sterilize implantable devices should be monitored by a Biological Indicator (along with a Chemical Indicator). The release decisions on such loads should be made based on the results of the cycle parameter readouts, the CI result AND the result for the Biological Indicator.

Chemical Indicators have a valid and useful role to play in the monitoring of sterilization cycles and they are often and appropriately used without a BI. However, all Chemical Indicators measure ONLY physical cycle parameters. FDA holds all Chemical Indicators to the same basic performance standards. We do not consider that one CI is "better" than another. Indeed, we do not permit "comparative claims". Hospitals have been making load release decisions based on CIs alone for many years for certain loads but requiring the use of a BI as well as as CI for other, specified loads such as loads with implants and loads used in qualification testing.

The Steris Verify SixCess CI is a Chemical Indicator. It may be used as you would use any other Chemical Indicator. However, it is NOT a Biological Indicator and should not be used in place of a BI.

I hope that this information will be of use. Please contact me should any further questions arise.