SBAR – Aesculap Tamper Evident Lock US910

Situation:

Asceulap external locks are used to identify when sterilized pans underwent low temperature sterilization and as tamper evident device to prevent reuse of pans. Department rounding by our ORTA team members identified several trays in Main OR core with a white indicator on the external lock, that had faded post sterilization. This caused confusion if the pans were sterilized or not.

Background:

The Aesculap tamper evident lock- (US910) is used as the external process indicator lock for Aesculap brand containers. These locks are used as a visual indicator to identify that the instrument tray has gone through the low temperature sterilization process.

These process indicator locks have a color change from Magenta to Blue once exposed to the appropriate sterilization modality.

Unexposed
(Not sterilized)

Exposed to
Sterilization

Fading of indicator to white
(post sterilization)

Assessment:

With review of the MIFU, it has been identified that these indicators may turn white post-sterilization due to uncontrolled temperatures or exposure to direct light.

From Aesculap SterilContainer System instructions for use

- Tamper Evident Lock US910 — Low Temperature external Chemical Indicators (CIs) are particularly sensitive and must be stored in a controlled room temperature, away from alkaline chemicals, acids and sources of light prior to use. DO NOT USE beyond the expiration date provided on the outside product packaging. Change of color prior to use in the sterilizer could indicate that these CIs were exposed to too much light or high temperatures during storage. After being processed, low temperature tamper evident lock should be stored at a controlled room temperature away from alkaline chemicals, acids and sources of light. Indicators may turn white post-sterilization if not stored out of direct lighting.

https://www.aesculapusaifus.com/MIFU

After consultation with the Quality and Safety Infection Prevention team and validation of the temperature and humidity logs kept within the OR sterile storage area where these pans are stored, it was determined that there were no major fluctuations in temperature within the space for 6-months since these trays were sterilized.

However, after reviewing the storage location of these instruments and proximity to the overhead lighting, it was determined that lighting was a contributor to the fading of the indicator lock. With the lighting being the contributor of the color change, and reviewing with infection prevention to assess the risk, it was determined the white color change does not pose a sterilization risk to the instrument tray or patient.

Recommendation:

Expected practice: If you find the Aesculap lock (US0910) with a white indicator, just like with other sterile instrument trays, make sure to check that all sterility quality checks are done. These checks include looking at the instrument tray package for any damage, checking if the external locks are secure, ensuring the filters are in the right place, and confirming the internal chemical indicator is within the acceptable color range. Once all these sterility quality checks are passed, it is safe to use the sterile instrument tray.