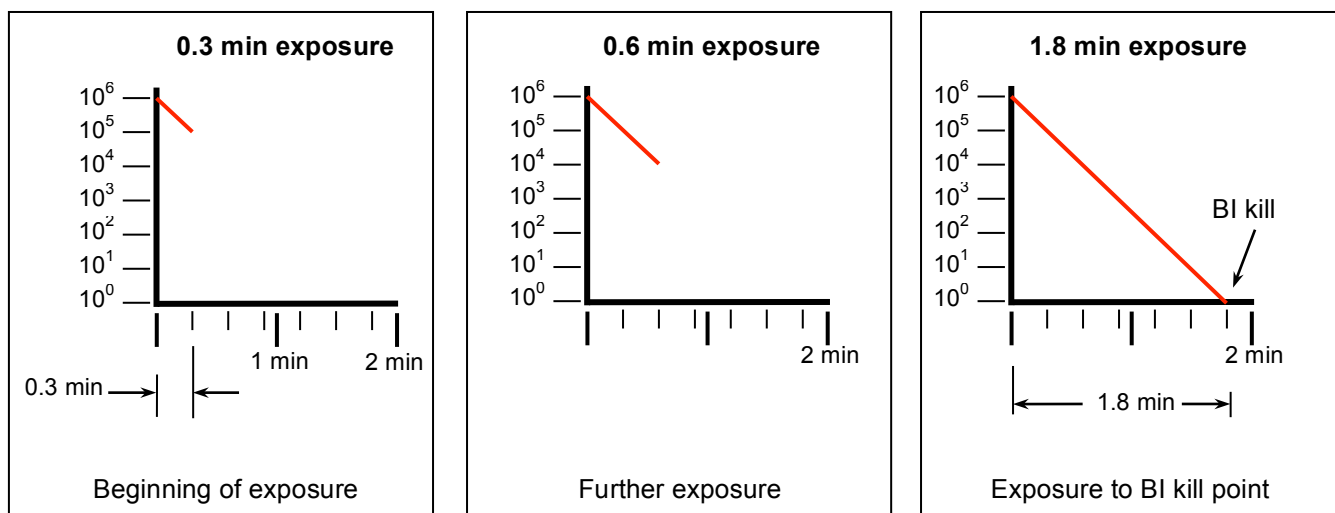


TECHNICAL BULLETIN

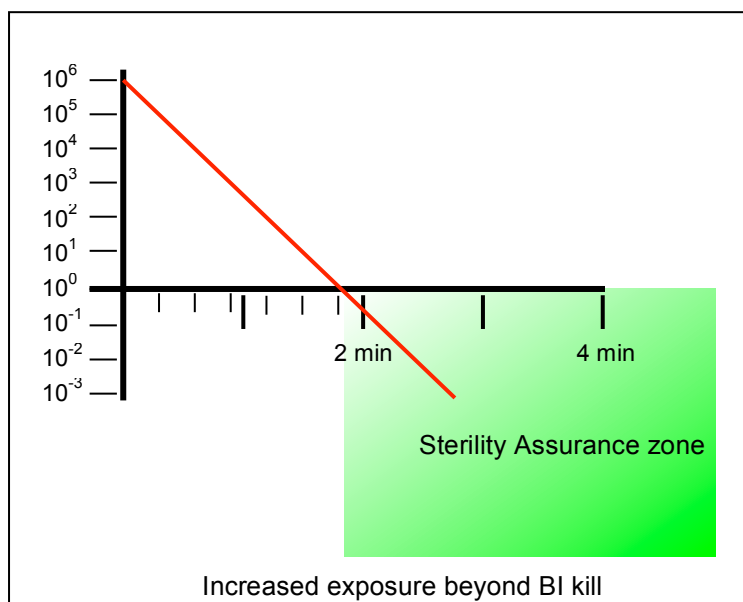
SAL 10^{-6}

The starting population of BIs is approximately 10^6 spores (one million). As BIs are exposed (to 270°F sterilizing steam in this example) the spores begin to die and the living population becomes lower and lower the longer they are exposed. The rate at which the living population decreases is given by the D value. If the D value is 0.3 minutes, then after 0.3 minutes of exposure, the living population of spores will be reduced by one log. In other words, the living population decreases from 10^6 to 10^5 in 0.3 minutes (18 seconds). If an additional 0.3 minutes of exposure follows the first, then the living population will be reduced by another log. This will continue as exposure time lengthens. Reduction of living population follows the graph below.

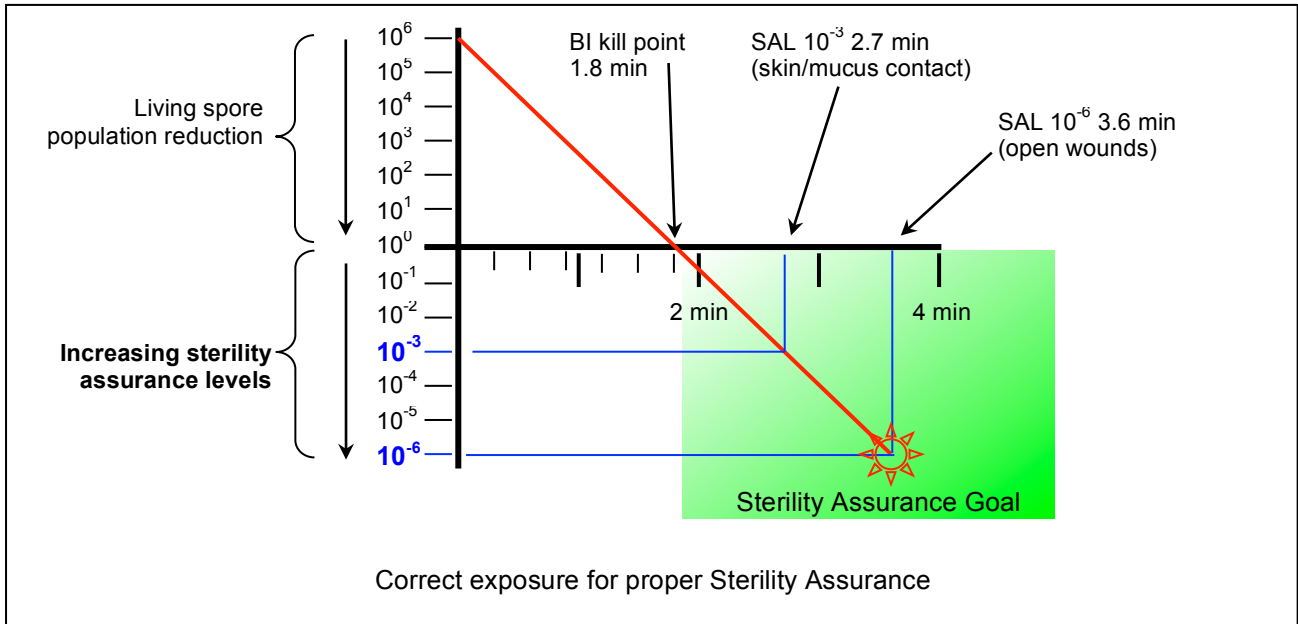


By the time 1.8 minutes has passed, all the living spores on the BIs have been killed. At this point, BIs have been sterilized and they no longer challenge the sterilizer cycle if further exposure is necessary.

The sterilization cycle can continue and should continue beyond this point. Further exposure to steam is a good thing. Further exposure increases the assurance that a condition of sterility will be achieved. For each 0.3 minutes of further exposure, one additional level of sterility assurance is obtained.



TECHNICAL BULLETIN



It has been established by FDA, AAMI, PDA, CDC and others that SAL 10^{-6} is the proper level of sterility assurance for surgical instruments and anything that comes in contact with open wounds. For items that come in contact with skin or mucus membranes, SAL 10^{-3} is appropriate. If BIs are no longer functioning beyond SAL 10^0 , how can the user verify that he/she has reached an exposure time that generates an SAL of 10^{-6} ? What tools are available? One could run a half cycle in the sterilizer with at least 3 BIs. If the BIs are dead, then it can be assumed that the full cycle will generate a condition of at least twice BI kill resulting in SAL 10^{-6} .

Another approach is to use chemical indicators that take longer to change color than it does to kill BIs in the sterilizer. Indicator timing of twice BI kill or more is the most helpful.

SteriTec

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