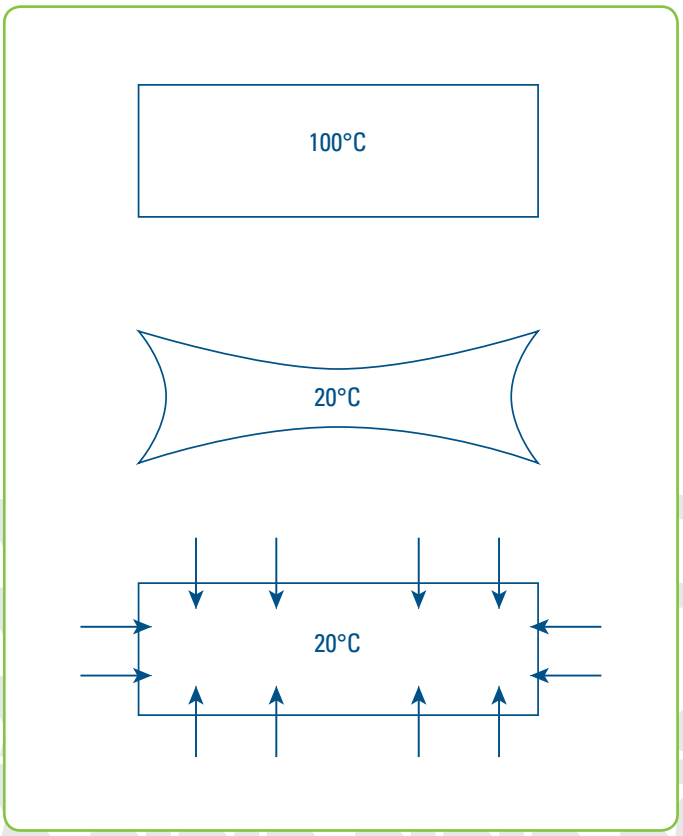
DETERMINATION OF THE MICROBIAL BARRIER PROPERTIES OF HALYARD ONE-STEP* STERILISATION WRAPPING MATERIAL USING THE FINAL PACK TEST METHOD[1]

BACKGROUND

The moment of the highest risk of contamination for a sterilised instrument set is during the removal from the autoclave. The package will cool down, this cooling down causes an under-pressure resulting in ambient air entering into the package.

The amount of airborne particles – including micro-organisms – that are entering the package depends on the barrier retention properties of the packaging material.

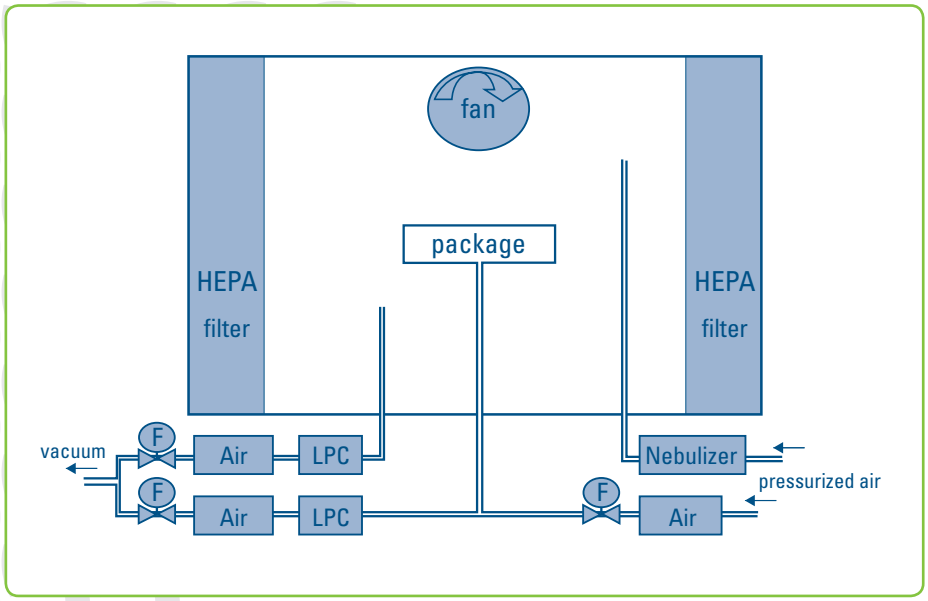


METHODOLOGY

Using this principle TNO, an independent research organisation based in the Netherlands, developed a bacterial barrier test. During the set-up of the test, the diffusional air flow rate is calculated: diffusional air flow represents the speed with which the air enters a sterilised package in the cooling down period. Diffusional flow was 250ml/minute for all types of HALYARD ONE-STEP* sterilisation material (H100, H200, H300, H400 and H500).

In the first phase, instrument trays were packaged in HALYARD ONE-STEP* sterilisation wrap (H100, H200, H300, H400 and H500) and sterilised at 134°C during 18 minutes (prion cycle).

After sterilisation the wrapped sets were challenged with an aerosol of latex particles of 1µm at set diffusional flow rate of 250ml/minute. The particle concentration of the aerosol surrounding the package and in the sterilised package was determined with a Laser Particle Counter (LPC).



In the second phase, sterilised instrument trays packaged in HALYARD ONE-STEP* Sterilisation Wrap (H100, H200, H300, H400 and H500) were cooled down to ambient temperature, the wrapped sets were stored for three months at ambient temperature. Within these three months the package was moved every two weeks. After the storage period the wrapped packages were submitted to the same test as mentioned above.

The bacterial barrier was calculated using following equation:

$$\frac{N_{\text{particles surrounding air}} - N_{\text{particles penetrating the package}}}{N_{\text{particles surrounding air}}} \times 100$$

CONCLUSION

1. The conclusion of phase 1 and 2 is similar: HALYARD ONE-STEP* sterilisation wrap has an average retention percentage of >99.99% at a diffusional flow rate of 250ml/minute. This is better than the (statistically) required ≥99.9%.
2. The prolonged sterilisation cycle of 18 minutes did not affect barrier properties of HALYARD ONE-STEP* sterilisation wrap.
3. The prolonged storage period of three months did not affect barrier properties of HALYARD ONE-STEP* sterilisation wrap.

HALYARD ONE-STEP* provides a barrier of >99.99% after the prolonged sterilisation cycle of 18 minutes and after 3 months of storage, helping to provide excellent instrument protection.

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References: 1. Data on file: TNO report V9520 – Determination of the microbial barrier properties of KIMGUARD* ONE-STEP* sterilisation wrap medical packaging material, type H100, H200, H300, H400 and H500 according to the Final Pack Method

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