This book chapter contains two studies, both sponsored by 3M Health Care, comparing the performance of Class 6 chemical indicators (CIs) with a Class 5 CI and three biological indicators (BIs) in detecting defined failure conditions in steam sterilization cycles.

**STUDY #1 – Air Leak Detection Capability of Various Steam Sterilization Indicators**

**Summary**

One of the conditions known to affect the efficacy of the steam sterilization process is the presence of air and/or non-condensable gases in the chamber. Inadequate air removal during the cycle conditioning phase has been cited as the greatest impediment to effective steam sterilization.

The performance of two Class 6 CIs in process challenge devices (PCDs), indicated for use in 270°F and 275°F cycles, and a self-contained BI in a PCD were compared in 270°F hospital type vacuum assisted steam sterilizer cycles with defined air leaks creating failure conditions. Both an air leak rate test and commercially available Bowie Dick type test packs were used to verify the presence of air in the chamber.

Two of the products evaluated in this study, the Rapid Readout BI PCD and the Class 6 Sheet PCD claim performance meeting or exceeding the performance of the AAMI 16 towel pack. However, all three products are recommended for use in routine monitoring and load release. Therefore, all of the products evaluated in this study would be expected to consistently detect the unacceptable levels of air in the air leak failure condition cycles.

**Results**

In cycles with no intentional air leak, all of the sterilization indicators evaluated in the study correctly indicated acceptable conditions for those cycles, i.e., pass Class 6 CI PCD results and a negative BI PCD result. However, in the two cycles with defined air leaks, only the BI PCD consistently detected the failure conditions by demonstrating positive results. (see Figure to right)

The Class 6 Card PCD did not detect the failure condition in any of the air leak test cycles (0/8) while only 2 of the 24 samples of the Class 6 Sheet PCD indicated a fail result in the air leak cycles (<10%). In the combined air leak cycles 21 of 24 (87.5%) BI PCD’s were fluorescent positive after 3 hrs. of incubation.

**Conclusions**

The BI PCD showed a greater sensitivity than either of the Class 6 PCDs in detecting the presence of air in the sterilizer chamber. Since the sterilizer instrumentation used in this study did not indicate unacceptable temperature or pressure readings, the only practical indication of the failure condition in these cycles would be provided by the sterilization indicators. These results suggest that the Class 6 PCDs, used as the only sterilization indicator in a dynamic air removal steam sterilization cycle, may not alert the user to failure conditions resulting from presence of chamber air in that cycle.