Identifying Causes of Steam Sterilization Process Failures

Human Errors

Incorrect use and interpretation of monitoring tools
- Not determining that the physical monitors were correct for the load
- Not identifying that the correct cycle was run for the load contents
- Using the wrong BI/PCD for the load
- Using the wrong Class 5 integrating indicator/PCD for the load
- Not following the BI/PCD or Class 5 integrating indicator instructions for use
- Incorrect reading of Class 5 integrating indicator or BI result
- Using the wrong internal chemical indicator for the cycle
- Incorrect reading of internal chemical indicator
- Incorrect storage of any chemical or biological indicators

Improper cycle for the load contents
- Not following the container or instrument/container manufacturers’ instructions for use
- Not verifying instrument/container manufacturers’ sterilization parameters for use in your sterilizers using AAMI product testing protocol. (1,2,3)

Incorrect packaging materials or packaging technique
- Incorrect packing or container system for the cycle parameters
- Not correctly preparing the container for use (i.e., filters and valves or appropriate bottom tray)
- Using an oversized wrap for application
- Not using a mesh bottom perforated tray that allows air removal and steam penetration
- Placing a paper-plastic pouch inside a container system or wrapped tray
- Placing a folded paper-plastic pouch inside another paper-plastic pouch
- Preparing textile packs that are too dense to sterilize in the cycle parameters chosen
- Not placing basins in same direction
- Not using non-linting absorbent material between nested basins
- Not disassembling or opening hinged instruments or surgical supplies
- Not holding packaging materials at 68°F-73°F (20°C-23°C), 30-60% RH for 2 hours prior to use

Sterilizer loading
- Stacking container systems if not recommended by manufacturer
- Stacking perforated instrument trays
- Not laying instrument trays flat or parallel to the shelf
- Laying peel pouches flat instead of on edge; not properly spaced or with plastic sides not facing one direction
- Not placing basins on edge
- Not placing fabric packs on edge
- Placing packages too close to each other impeding air removal and sterilant penetration around and through load

Poor Steam Quality or Quantity

Wet steam
- Improperly insulated steam lines
- Malfunctioning or missing trap in steam line
- Malfunctioning or no drain check valve
- Steam contact with a cold load
- Too much water in steam produced at boiler

Continued on reverse
Poor Steam Quality or Quantity (cont.)

Superheated steam
- Improper chamber heat up
- Desiccated packaging materials (e.g., towels)
- Steam pressure too low for the temperature
- Excessive reduction of steam pressure too close to sterilizer
- Faulty steam control valve
- Faulty pressure reducer control valve

Other reasons
- Variations in steam pressure due to clogged filter, poorly engineered piping or excessive demands
- Pressure gauges and controllers out of calibration
- Clogged steam lines
- Clogged steam supply strainer
- Clogged chamber drain line, strainer or chamber drain screen
- Malfunctioning valves

Incomplete Air Removal
- Inadequate vacuum or vacuum depth or other air removal system
- Clogged chamber drain line, strainer or chamber drain screen
- Clogged vent lines
- Leak caused by a faulty door gasket
- Leak in other areas of chamber
- Plugged, faulty or maladjusted control valves
- Low steam pressure

- Too high water temperature
- Inadequate water supply pressure
- Clogged water supply strainer
- Air trapped by the load
- Incorrect cycle parameters for the load

Inadequate Cycle Temperature
- Temperature gauge out of calibration
- Long heat-up time of large loads (i.e., heat lag)
- Clogged chamber drain line, strainer or chamber drain screen
- Variations in steam pressure due to clogged filter, poorly engineered piping or excessive demands on the steam supply
- Presence of non-condensable gases in steam line and load
- Inadequate steam supply pressure
- Clogged steam supply strainer

Insufficient Time at Temperature
- Control timer out of calibration
- Inappropriate cycle parameters for the load being processed
- Come up time less than 1.5 minutes in a gravity 270°F to 275°F (132°C to 135°C) 3 minute cycle
- Oversized load