Identifying Causes of Steam Sterilization Process Failures

Key variables to consider when investigating a steam sterilization process failure

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 CSA product testing protocol.

Inappropriate 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

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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

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