relationships obtained using F value calculations can design optimal sterilization cycles using any temperature profile usually within $\pm$ 10°C of 121°C.

HEAT STERILIZATION

Heat used to sterilize items is either wet heat or dry heat. Wet heat is also known as steam sterilization, steam under pressure sterilization, or autoclaving. Items traditionally sterilized by steam under pressure include rubber and durable plastic materials (e.g., filtration and tubing materials are durable whereas flexible plastic containers are not), mixing tanks, other equipment parts, filling equipment, freeze-dryer chambers, and, if possible, filled containers with product if the product can withstand high-temperature exposure.

Items sterilized by dry heat include glass containers, stainless steel equipment, and dry powders, again if the powder can withstand high-temperature exposure.

Lethality of microorganisms depends on the degree of heat exposure, duration of heat exposure, and moisture. Heat destruction of microorganisms occurs by coagulation of the proteins in the cell. Moist heat is much more effective as a sterilization method than dry heat. Moist heat involves raising the boiling point of water from 100°C to 121°C by applying 15 pounds per square inch pressure above atmospheric pressure. At this pressure and temperature water becomes saturated steam. Sterilization by moist heat means that liquid water is essential for denaturation of proteins in the bacterial cell wall. When saturated steam hits a surface cooler than itself, temperature of the surface increases and with this increase there is a release of what is called heat of condensation. The heat of condensation results from the need for a phase change to maintain the balance of liquid water in saturated steam. Heat of condensation releases a huge amount of energy (hundreds of calories) and this energy is what kills microorganisms so effectively. By contrast, dry heat at the same temperature will only release about 1 calorie per gram. Therefore, the presence of liquid water is essential for the effective microbial destructive effects of moist heat sterilization; therefore, oils or enclosed dry systems cannot effectively be terminally sterilized by wet heat. Dry heat will work but must use much higher temperatures to compensate for the lack of the heat of condensation energy effect.

Steam (Wet Heat) Sterilization

Steam sterilization is conducted in a pressurized vessel called an autoclave. Steam must be pure and saturated with no air or other noncondensable gases. The problem of removing air from the chamber and replacing it with pure saturated steam is the greatest challenge in effective steam sterilization. Keep in mind that thermocouples used to monitor temperature at various locations in the chamber and within the items being sterilized cannot detect whether the atmosphere is wet or dry heat. Other indicators called Bowie–Dick (Fig. 17-6) or Dart indicators are used to verify that the temperature measured is steam heat, not dry heat. If adequate steam penetration has occurred, dark brown stripes will appear across the Bowie–Dick tape. If the stripes are pale brown, steam penetration is inadequate and the heat in that area has been dry not wet. These indicators are used as part of other measurements—temperature, pressure, biological indicators—to validate a successful sterilization cycle.

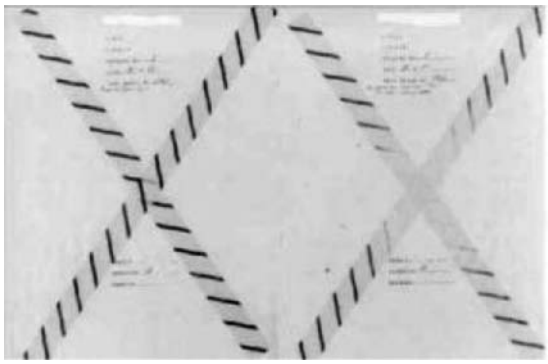

Figure 17-6 Bowie–Dick physical indicators of exposure to steam or dry heat. Bowie–Dick tape showing dark brown stripes (left) and stripes not all dark brown (right) indicating that the item on the right has not been adequately steam sterilized.