(A)

(B)

Figure 19-9 Examples of aluminum–plastic seals. (A) Flip-Off® (Flip-Off® is a registered trademark of West Pharmaceutical Services in the United States and other jurisdictions) seals: aluminum shell with a removable plastic button in order to access stopper surface. (B) Flip-Tear seals: aluminum shell is completely removed from container by flipping off the plastic button that allows stopper removal. *Source*: Courtesy of West Pharmaceutical Services.

Problems encountered during stoppering include the following:

- Too little or too much silicone on stoppers
- Misaligned or bent syringe stopper insertion rods or tubes
- Stoppers become jammed on the track
- Improper headspace (syringes)
- Stoppers are not completely seated.

SEALING

Ampoule-filled containers should be sealed as soon as possible to prevent the contents from being contaminated by the environment. Ampoules are sealed by melting a portion of the glass neck. Two types of seals are employed normally: tip seals (bead seals) or pull seals (Fig. 19-10).

Tip seals are made by melting enough glass at the tip of the neck of an ampoule to form a bead and close the opening. These can be made rapidly in a high-temperature gas-oxygen flame. To produce a uniform bead, the ampoule neck must be heated evenly on all sides, such as by burners on opposite sides of stationary ampoules or by rotating the ampoule in a single flame. Care must be taken to adjust the flame temperature and the interval of heating properly to completely close the opening with a bead of glass. Excessive heating will result in the expansion of the gases within the ampoule against the soft bead seal and cause a bubble to form. If it bursts, the ampoule is no longer sealed; if it does not, the wall of the bubble will be thin and fragile. Insufficient heating will leave an open capillary through the center of the bead. An incompletely sealed ampoule is called a leaker.

Pull seals are made by heating the neck of the ampoule below the tip, leaving enough of the tip for grasping with forceps or other mechanical devices. The ampoule is rotated in the flame from a single burner. When the glass has softened, the tip is grasped firmly and pulled quickly away from the body of the ampoule, which continues to rotate. The small capillary tube thus formed is twisted closed. Pull sealing is slower, but the seals are more sure than tip sealing.

Powder ampoules or other types having a wide opening must be sealed by pull sealing. Fracture of the neck of ampoules during sealing may occur if wetting of the necks occurred at the time of filling. Also, wet necks increase the frequency of bubble formation and unsightly carbon deposits if the product is organic.