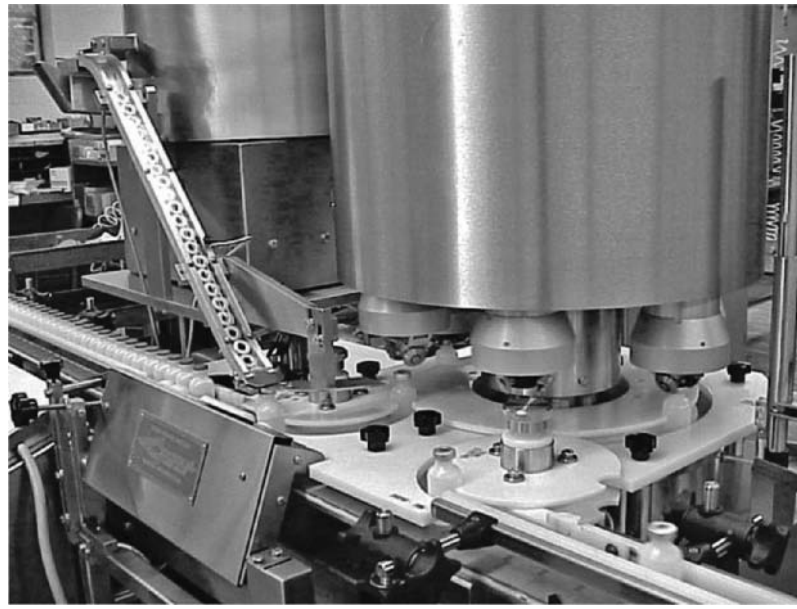

Figure 19-11 CM200 continuous motion crimping machine. *Source*: Courtesy of Cozzoli Machine Company.

The aluminum caps are so designed that the outer layer of double-layered caps, or the center of single-layered caps, can be removed to expose the center of the rubber closure without disturbing the band that holds the closure in the container. Rubber closures for use with intravenous administration sets often have a permanent hole through the closure. In such cases, a thin rubber disk overlayed with a solid aluminum disk is placed between an inner and outer aluminum cap, thereby providing a seal of the hole through the closure.

Single-layered aluminum caps may be applied by means of a hand crimper known as the Fermpress (suppliers: *West, Wheaton*). Double- or triple-layered caps require greater force for crimping; therefore, heavy-duty mechanical crimpers (Fig. 19-11) are required (suppliers: *Bosch, Cozzoli, Perry, West, Wheaton*).

A relatively recent trend, although now standard practice, is the requirement that sealing of vials and other containers be accomplished in Class 100/Grade A/ISO 5 clean room environments. Formerly such sealing occurred in unclassified environments.

ADVANCES IN VIAL AND SYRINGE FILLING

While the emphasis of this entire book is sticking to the basics, some discussion of advances (3,4) need to be mentioned although at the time of finishing this writing, it is unclear how routine these advances will become.

Flexible Lines

Because of extremely high costs of some new drugs, especially biopharmaceuticals, it is preferable to fill small batches to reduce the risk of unacceptable monetary losses in the event of a manufacturing deviation that results in batch rejection. The move toward smaller batch filling has necessitated the requirement for more accurate fills and faster line change overs. One way that this is accomplished is through the use of single-use, disposable closing systems[2] in which the entire product path is discarded after use. Another approach is to modify filling designs so that only one change part is required for a vial diameter change. Filling machines are available that have more than one dosing system to increase flexibility for filling a variety of products.

[2] For example, the Acerta® DS1 dispensing system.