

- Availability of enormous (millions) quantities of presterilized ready-to-fill syringes such as BD Hypak[®] SCF and BunderGlas RTF
- The advent of contract manufacturers specializing in syringe processing with lower costs and high-speed filling equipment
- Elimination of dosage errors because unlike vials, syringes contain the exact amount of deliverable dose needed
- Ease of administration because of elimination of several steps required before injection of a drug contained in a vial. Because fewer manipulations are required, sterility assurance is increased
- More convenient for health care professionals and end users; easier for home use; easier in emergency situations
- Reduction of medication errors, misidentification; better dose accuracy
- Better use of controlled drugs such as narcotics
- Lower injection costs—less preparation, fewer materials, easy storage, and disposal
- Elimination of vial overfill for products transferred to syringes for direct injection or addition to primary diluents.

Syringe barrels can either be glass or plastic while syringe plunger rods are usually plastic. Plastic polymers for the syringe barrel include polypropylene, polyethylene, and polycarbonate. However, newer technologies are being developed in the area of “glass-like” composite materials.

Syringes with needles may also have needle protectors (Fig. 4-5) to avoid potential dangers of accidental needle sticks postadministration. Such protectors either can be part of the assembly or can be assembled during the finishing process. The use of these protection devices is increasing due to the 2001 United States Federal Needle Stick Safety and Prevention Act (7). Needle stick prevention can be manual (shield activated manually by the user although there can be risk of accidental sticking), active (automated needle shielding activated by user), or passive (automated needle shielding without action by the user).

Issues that must be addressed in selecting and qualifying components of a syringe include

- Container/closure integrity testing
- Plastic component extractables
- Sterilizability, especially if needle is part of the package to be sterilized
- Siliconization of barrel and plunger (although silicone-free syringes now exist that provide both lubricity and inert drug-contact surfaces)
- Compatibility of product with syringe contact parts, especially the rubber plunger



Figure 4-5 Syringe with needle guard. *Source:* Courtesy of © Becton, Dickinson and Company.